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FEDERAL REGISTER

VOLUME 29 NUMBER 204

Washington, Saturday, October 17, 1964

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FEDERAL REGISTER

Area Code 202 Phone 963-3261

Published daily, Tuesday through Saturday (no publication on Sundays, Mondays, or on the day after an official Federal holiday), by the Office of the Federal Register, National Archives and Records Service, General Services Administration (mail address National Archives Building, Washington, D.C. 20408), pursuant to the authority contained in the Federal Register Act, approved July 26, 1935 (49 Stat. 500, as amended; 44 U.S.C., ch. 8B), under regulations prescribed by the Administrative Committee of the Federal Register, approved by the President (1 CFR Ch. I). Distribution is made only by the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402.

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Rules and Regulations

Title 4—ACCOUNTS

Chapter I—General Accounting Office

SUBCHAPTER D—TRANSPORTATION

PART 51—PASSENGER TRANSPORTATION SERVICE FOR THE ACCOUNT OF THE UNITED STATES

Use of Designated Agents

A new § 51.22a is added to permit the signing of transportation requests by designated agents.

Section 51.22a is added as follows:

§ 51.22a Use of designated agents.

When the head of a department, agency, or other establishment of the United States Government determines that it is in the interest of more economical and efficient procurement of passenger transportation, persons named by him as "designated agents" may sign transportation requests in lieu of travelers.

[SEAL] JOSEPH CAMPBELL,
Comptroller General of the United States.

[F.R. Doc. 64-10623; Filed, Oct. 16, 1964; 8:47 a.m.]

Title 7—AGRICULTURE

Subtitle A—Office of the Secretary of Agriculture

[Amdt. 9]

PART 7—AGRICULTURAL STABILIZATION AND CONSERVATION COMMITTEES

Subpart—Selection and Functions of Agricultural Stabilization and Conservation County and Community Committees

ELIGIBILITY AND REMOVAL FROM OFFICE OR EMPLOYMENT

By virtue of the authority vested in the Secretary of Agriculture by the Soil Conservation and Domestic Allotment Act of 1936, as amended, the regulations in this subpart published in the FEDERAL REGISTER of March 23, 1961 (26 F.R. 2451), June 22, 1961 (26 F.R. 5555), April 25, 1962 (27 F.R. 3911), July 21, 1962 (27 F.R. 6921), November 16, 1962 (27 F.R. 11312), March 1, 1963 (28 F.R. 1979), July 11, 1963 (28 F.R. 7067), August 10, 1963 (28 F.R. 8239), and October 9, 1963 (28 F.R. 10813) are further amended to: (1) Eliminate excess wording and improve clarity; (2) eliminate the word "seriously" §§ 7.15, 7.16, 7.28, 7.29, and 7.30; (3) eliminate in the foregoing sections provision that fraud committed, attempted, or conspired, must have been in the conduct of the person's office or employment; (4) add as a basis for disqualifying a former committeeman or employee for future service or employment the same reasons, except incompetency, used to suspend and remove a current committeeman or employee; (5) eliminate in § 7.29 that the county office manager will act on a response to an employee suspended by him and provide that the county committee will receive and act on such a response; (6) add new paragraphs to §§ 7.28 and 7.29 concerning suspension and removal of a committeeman or employee who, prior to becoming such, committed, attempted, or conspired to commit fraud, or who impeded the effectiveness of programs administered in the county; and (7) change § 7.31 from "Right of appeal" to "Right of review." The regulations in this subpart are, therefore, amended as follows:

ELIGIBILITY REQUIREMENTS

§ 7.15 County committeemen, community committeemen, and delegates.

* * * * *

(e) Not have been removed as a county committeeman, community committeeman, delegate, alternate to any such office, or as an employee for failure to perform the duties of his office, or committing, or attempting, or conspiring to commit fraud, or incompetency, or impeding the effectiveness of any program administered in the county, unless such disqualification is waived by the State committee or the Deputy Administrator;

(f) Not have been disqualified for future service because of a determination by a State committee that during previous service as a county committeeman, community committeeman, delegate, alternate to any such office, or as an employee, he failed to perform the duties of his office or employment, or he committed, attempted, or conspired to commit fraud, or he impeded the effectiveness of any program administrered in the county, unless such disqualification is waived by the State committee or the Deputy Administrator;

* * * * *

§ 7.16 All other personnel.

* * * * *

(c) The county office manager or any other employee must not have been removed as a county committeeman, community committeeman, delegate, alternate to any such office, county office manager, or other employee for failure to perform the duties of his office, or committing, or attempting, or conspiring to commit fraud, or incompetency, or impeding the effectiveness of any program administered in the county, unless such disqualification is waived by the State committee or the Deputy Administrator;

(d) The county office manager and other employees must not have been disqualified for future employment, because of a determination by a State committee that during previous service as a county committeeman, community committeeman, delegate, alternate to any such office, or as an employee, he failed to perform the duties of his office or employment, or he committed, attempted, or conspired to commit fraud, or he impeded the effectiveness of any program administered in the county, until such disqualification is waived by the State committee or the Deputy Administrator.

* * * * *

REMOVAL FROM OFFICE OR EMPLOYMENT

§ 7.28 County and community committeemen, and delegates to county convention.

(a) Any county committeeman, community committeeman, delegate to the county convention, or any alternate to any such office, who fails to perform the duties of his office, or who commits, or attempts, or conspires to commit fraud, or is incompetent, or who impedes the effectiveness of any program administered in the county, or who violates the provisions of § 7.27 (e) or (f), shall be suspended by the State committee. Any such person who is under formal investigation for any of the above cited reasons may be suspended by the State committee. Any person suspended under the provisions of this paragraph shall be given a written statement of the reasons for such action and 15 days from the date of mailing in which to advise the State committee in writing, in person, or both, why he should be restored to duty. The State committee, following such further investigation as is deemed necessary, shall either restore to duty or remove the suspended person. In the event further investigation develops reasons, in addition to those disclosed in the suspension notice, for the action taken, the suspended person shall be given written notification of such additional reasons and 15 days from the date of mailing in which to advise the State committee why he should be restored to duty. In the event a person under suspension submits his resignation, or his term expires, acceptance thereof shall not prevent a determination by the State committee that he would have been removed had he remained in the position, and such a determination shall constitute removal within the meaning of §§ 7.15(e), 7.16(c), and 7.31. The person so removed shall be given written notification of any such determination and the reasons therefor.

* * * * *

(c) Any former county committeeman, community committeeman, delegate, or any alternate to any such office, who during such term of office failed to perform the duties of his office, or committed, attempted, or conspired to commit fraud, or who impeded the effectiveness of any program administered in the county, or who violated the provisions of § 7.27 (e) or (f) may be disqualified from future service or employment by the State committee. Before any such dis-

qualification determination is made, the State committee shall undertake such investigation as it deems necessary after which the State committee shall give the affected person a written statement of reasons for the proposed disqualification action. Such person shall have 15 days from the date of mailing to advise in writing, in person, or both, why the action should not be taken. If any further investigation develops substantial additional reasons for disqualification, the person involved shall be given a written statement of such reasons and 15 days from the date of mailing in which to respond.

(d) Any county committeeman, community committeeman, delegate to the county convention, or any alternate to any such office, who, prior to taking his present office, committed, or attempted, or conspired to commit fraud, or who impeded the effectiveness of any program administered in the county, may be suspended by the State committee. Any such person who is under formal investigation for any of the above cited reasons may be suspended by the State committee. The proceedings under this paragraph shall be the same as in paragraph (a) of this section.

§ 7.29 County office personnel.

(a) Any county office manager who fails to perform the duties of his employment, or who commits, or attempts, or conspires to commit fraud, or is incompetent, or who impedes the effectiveness of any program administered in the county, or who violates the provisions of § 7.27 (e) or (f), shall be suspended by the county committee, or State committee. Any county office manager who is under formal investigation for any of the above cited reasons may be suspended by the county committee or State committee. A person suspended under the provisions of this paragraph shall be given a written statement of the reasons for such action and 15 days from the date of mailing in which to advise the committee which made the suspension, in writing, in person, or both, why he should be restored to duty. The committee which made the suspension following such further investigation as is deemed necessary, shall either restore to duty or remove the suspended person; except that, the county committee may not restore a suspended person to duty without prior written approval of the State committee, and upon refusal of such approval shall promptly remove such person. Upon refusal or failure of the county committee promptly to remove the suspended person, the State committee shall remove such person. In the event further investigation develops reasons, in addition to those disclosed in the suspension notice, for the action taken, the suspended person shall be given written notification of such additional reasons and 15 days from the date of mailing in which to advise why he should be restored to duty. In the event a person under suspension submits his resignation, acceptance thereof shall not prevent a determination by the county committee, or State committee, that he would have been removed had he remained in the position, and such a determination shall constitute removal within the meaning of §§ 7.15(e), 7.16(c), and 7.31. The person so removed shall be given written notification of any such determination and the reasons therefor.

(b) Any employee, other than the county office manager, who fails to perform the duties of his employment, or who commits, or attempts, or conspires to commit fraud, or is incompetent, or who impedes the effectiveness of any program administered in the county, or who violates the provisions of § 7.27 (e) or (f), shall be suspended by the county office manager, county committee, or State committee. Any employee who is under formal investigation for any of the above cited reasons may be suspended by the county office manager, county committee, or State committee. A person suspended under the provisions of this paragraph shall be given a written statement of the reasons for such action and 15 days from the date of mailing in which to advise the county committee, or the State committee if it made the suspension, in writing, in person, or both, why he should be restored to duty. The county committee, or the State committee if it made the suspension, following such further investigation as is deemed necessary, shall either restore to duty or remove the suspended person; except that, the county committee may not restore a suspended person to duty without prior written approval of the State committee, and upon refusal of such approval shall promptly remove such person. Upon refusal or failure of the county committee promptly to remove the suspended person, the State committee shall remove such person. In the event further investigation develops reasons, in addition to those disclosed in the suspension notice, for the action taken, the suspended person shall be given written notification of such additional reasons and 15 days from the date of mailing in which to advise why he should be restored to duty. In the event a person under suspension submits his resignation, acceptance thereof shall not prevent a determination by the county committee, or the State committee, that he would have been removed had he remained in the position and such a determination shall constitute removal within the meaning of §§ 7.15(e), 7.16(c), and 7.31. The person so removed shall be given written notification of any such determination and the reasons therefor.

(c) Any former county office manager or other employee who during his term of employment failed to perform the duties of his employment, or who committed, attempted, or conspired to commit fraud, or who impeded the effectiveness of any program administered in the county, or who violated the provisions of § 7.27(e) or (f), may be disqualified from future service or employment by the State committee. Before any such disqualification determination is made, the State committee shall undertake such investigation as it deems necessary, after which the State committee shall give the affected person a written statement of reasons for the proposed disqualification action. Such person shall have 15 days from the date of mailing to advise in writing, in person, or both, why the action should not be taken. If any further investigation develops substantial additional reasons for disqualification, the person involved shall be given a written statement of such reasons and 15 days from the date of mailing in which to respond.

(d) Any county office manager who, prior to taking his present office or employment, committed, or attempted, or conspired to commit fraud, or who impeded the effectiveness of any program administered in the county, may be suspended by the county committee or State committee. Any county office manager who is under formal investigation for any of the above cited reasons may be suspended by the county committee or State committee. The proceedings under this paragraph shall be the same as in paragraph (a) of this section.

(e) Any employee, other than the county office manager, who, prior to taking his present office or employment, committed, or attempted, or conspired to commit fraud, or who impeded the effectiveness of any program administered in the county, may be suspended by the county office manager, county committee, or State committee. Any employee who is under formal investigation for any of the above cited reasons may be suspended by the county office manager, county committee, or State committee. The proceedings under this paragraph shall be the same as in paragraph (b) of this section.

§ 7.30 Delegation of authority to deputy administrator.

Notwithstanding the authority vested in the State committee, a county committee, and the county office manager by these regulations, the Deputy Administrator shall have authority to suspend and remove any county committeeman, community committeeman, delegate to the county convention, an alternate to any such office, county office manager, or other county employee, for any and all of the reasons and causes authorizing such suspension and removal by the State committee, the county committee, or the county office manager. When the Deputy Administrator suspends any person hereunder he shall give a written statement of the reasons for such action. Any person suspended shall have 15 days from date of mailing in which to advise the Deputy Administrator in writing, in person, or both, why he should be restored to duty. The Deputy Administrator following such further investigation as he deems necessary shall either restore to duty or remove the suspended person. In the event further investigation develops reasons for the action taken, in addition to those disclosed in the suspension notice, the suspended person shall be given written notification of such additional reasons and 15 days from date of mailing within which to advise the Deputy Administrator why he should be restored to duty.

§ 7.31 Right of review.

Any person removed from employment by the county committee under the provisions of § 7.29 (a) or (b), or § 7.27 (e) or (f) shall have the right to present to the State committee reasons in writing, in person, or both, as to why he should be restored to duty. The State committee may either uphold the decision of the county committee or order the person restored to duty. If the person removed is dissatisfied with the decision of the State committee, he may present the reasons in writing, in person, or both, to the Deputy Administrator as to why he should be restored to duty. The Deputy Administrator may uphold the decision of the county committee or order the person restored to duty. Any person removed from office or employment or disqualified for future office or employment by the State committee under the provisions of §§ 7.27 (e) and (f), 7.28, 7.29, or 7.30 shall have the right to present to the Deputy Administrator reasons in writing, in person, or both, as to why he should be restored to duty or have the disqualification removed. The Deputy Administrator may uphold the decision or order the person restored to duty, or order the disqualification removed. Any person removed from office or employment by the Deputy Administator under the provisions of § 7.30 shall have the right to request the Deputy Administrator for a reconsideration of his decision and to present reasons therefor in writing, in person, or both. Any presentation shall be in accordance with such procedure as the Deputy Administrator may prescribe. Notice of any presentation under this section must be filed within 30 days of the date the notice of removal or disqualification decision is mailed to any such person.

CHARLES S. MURPHY,
Acting Secretary.

OCTOBER 13, 1964.

[F.R. Doc. 64-10640; Filed, Oct. 16, 1964; 8:49 a.m.]

Chapter IX—Agricultural Marketing Service (Marketing Agreements and Orders; Fruits, Vegetables, Tree Nuts), Department of Agriculture

[Tangerine Reg. 20]

PART 905—ORANGES, GRAPEFRUIT, TANGERINES, AND TANGELOS GROWN IN FLORIDA

Limitation of Shipments

§ 905.429 Tangerine Regulation 20.

(a) *Findings.* (1) Pursuant to the marketing agreement, as amended, and Order No. 905, as amended (7 CFR Part 905), regulating the handling of oranges, grapefruit, tangerines, and tangelos grown in Florida, effective under the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), and upon the basis of the recommendations of the committees established under the aforesaid amended marketing agreement and order, and upon other available information, it is hereby found that the limitation of shipments of tangerines, as hereinafter provided, will tend to effectuate the declared policy of the act.

(2) It is hereby further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rule making procedure, and postpone the effective date of this section until 30 days after publication thereof in the FEDERAL REGISTER (5 U.S.C. 1001–1011) because the time intervening between the date when information upon which this section is based became available and the time when this section must become effective in order to effectuate the declared policy of the act is insufficient; a reasonable time is permitted, under the circumstances, for preparation for such effective time; and good cause exists for making the provisions hereof effective as hereinafter set forth. Shipments of tangerines, grown in the production area, are presently subject to regulation by grades and sizes, pursuant to the amended marketing agreement and order; the recommendation and supporting information for regulation during the period specified herein were promptly submitted to the Department after an open meeting of the Growers Administrative Committee on October 13, 1964, such meeting was held to consider recommendations for regulation, after giving due notice of such meeting, and interested persons were afforded an opportunity to submit their views at this meeting; the provisions of this section, including the effective time hereof, are identical with the aforesaid recommendation of the committee, and information concerning such provisions and effective time has been disseminated among handlers of such tangerines; it is necessary, in order to effectuate the declared policy of the act, to make this section effective during the period hereinafter set forth so as to provide for the continued regulation of the handling of tangerines, and compliance with this section will not require any special preparation on the part of the persons subject thereto which cannot be completed by the effective time hereof.

(b) *Order.* (1) Terms used in the amended marketing agreement and order shall, when used herein, have the same meaning as is given to the respective term in said amended marketing agreement and order; and terms relating to grade, diameter, and standard pack, as used herein, shall have the same meaning as is given to the respective term in the United States Standards for Florida Tangerines (§§ 51.1810–51.1834 of this title).

(2) During the period beginning at 12:01 a.m., e.s.t., October 19, 1964, and ending at 12:01 a.m., e.s.t., November 16, 1964, no handler shall ship between the production area and any point outside thereof in the continental United States, Canada, or Mexico:

(i) Any tangerines, grown in the production area, which do not grade at least U.S. No. 1 Russet; or

(ii) Any tangerines, grown in the production area, which are of a size smaller than 2$\frac{6}{16}$ inches in diameter, except that a tolerance of 10 percent, by count, of tangerines smaller than such minimum diameter shall be permitted, which tolerance shall be applied in accordance with the provisions for the application of tolerances specified in said United States Standards for Florida Tangerines.

(Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674)

Dated: October 15, 1964.

PAUL A. NICHOLSON,
Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[F.R. Doc. 64-10652; Filed, Oct. 16, 1964; 8:50 a.m.]

[Tangelo Reg. 21]

PART 905—ORANGES, GRAPEFRUIT, TANGERINES, AND TANGELOS GROWN IN FLORIDA

Limitation of Shipments

§ 905.430 Tangelo Regulation 21.

(a) *Findings.* (1) Pursuant to the marketing agreement, as amended, and Order No. 905, as amended (7 CFR Part 905), regulating the handling of oranges, grapefruit, tangerines, and tangelos grown in Florida, effective under the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), and upon the basis of the recommendations of the committees established under the aforesaid amended marketing agreement and order, and upon other available information, it is hereby found that the limitation of shipments of tangelos, as hereinafter provided, will tend to effectuate the declared policy of the act.

(2) It is hereby further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rule making procedure, and postpone the effective date of this section until 30 days after publication thereof in the FEDERAL REGISTER (5 U.S.C. 1001–1011) because the time intervening between the date when information upon which this section is based became available and the time when this section must become effective in order to effectuate the declared policy of the act is insufficient; a reasonable time is permitted, under the circumstances, for preparation for such effective time; and good cause exists for making the provisions hereof effective as hereinafter set forth. Shipments of tangelos, grown in the production area, are presently subject to regulation by grades and sizes, pursuant to the amended marketing agreement and order; the recommendation and supporting information for regulation during the period specified herein were promptly submitted to the Department after an open meeting of the Growers Administrative Committee on October 13, 1964, such meeting was held to consider recommendations for regulation, after giving due notice of such meeting, and interested persons were afforded an opportunity to submit their views at this meeting; the provisions of this section, including the effective time hereof, are identical with the aforesaid recommendation of the

committee, and information concerning such provisions and effective time has been disseminated among handlers of such tangelos; it is necessary, in order to effectuate the declared policy of the act, to make this section effective during the period hereinafter set forth so as to provide for the continued regulation of the handling of tangelos, and compliance with this section will not require any special preparation on the part of the persons subject thereto which cannot be completed by the effective time hereof.

(b) *Order.* (1) Terms used in the amended marketing agreement and order shall, when used herein, have the same meaning as is given to the respective term in said amended marketing agreement and order; and terms relating to grade, diameter, standard pack, and standard box, as used herein, shall have the same meaning as is given to the respective term in the United States Standards for Florida Oranges and Tangelos (§§ 51.1140–51.1178 of this title).

(2) During the period beginning at 12:01 a.m., e.s.t., October 19, 1964, and ending at 12:01 a.m., e.s.t., November 16, 1964, no handler shall ship between the production area and any point outside thereof in the continental United States, Canada, or Mexico:

(i) Any tangelos, grown in the production area, which do not grade at least U.S. No. 1 Russet; or

(ii) Any tangelos, grown in the production area, which are of a size smaller than 2$^{9}/_{16}$ inches in diameter, except that a tolerance of 10 percent, by count, of tangelos smaller than such minimum diameter shall be permitted, which tolerance shall be applied in accordance with the provisions for the application of tolerances specified in said United States Standards for Florida Oranges and Tangelos.

(Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674)

Dated: October 15 1964.

PAUL A. NICHOLSON,
Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[F.R. Doc. 64–10653; Filed, Oct. 16, 1964; 8:50 a.m.]

[Orange Reg. 41]

PART 905—ORANGES, GRAPEFRUIT, TANGERINES, AND TANGELOS GROWN IN FLORIDA

Limitation of Shipments

§ 905.428 Orange Regulation 41.

(a) *Findings.* (1) Pursuant to the marketing agreement, as amended, and Order No. 905, as amended (7 CFR Part 905), regulating the handling of oranges, grapefruit, tangerines, and tangelos grown in Florida effective under the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), and upon the basis of the recommendations of the committees established under the aforesaid amended marketing agreement and order, and upon other available information, it is hereby found that the limitation of shipments of oranges, including Temple oranges, as hereinafter provided, will tend to effectuate the declared policy of the act.

(2) It is hereby further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rule making procedure, and postpone the effective date of this section until 30 days after publication thereof in the FEDERAL REGISTER (5 U.S.C. 1001–1011) because the time intervening between the date when information upon which this section is based became available and the time when this section must become effective in order to effectuate the declared policy of the act is insufficient; a reasonable time is permitted, under the circumstances, for preparation for such effective time; and good cause exists for making the provisions hereof effective as hereinafter set forth. Shipments of oranges, except Temple oranges, grown in the production area, are presently subject to regulation by grades and sizes, pursuant to the amended marketing agreement and order; the recommendation and supporting information for regulation during the period specified herein were promptly submitted to the Department after an open meeting of the Growers Administrative Committee on October 13, 1964, such meeting was held to consider recommendations for regulation, after giving due notice of such meeting, and interested persons were afforded an opportunity to submit their views at this meeting; the provisions of this section, including the effective time hereof, are identical with the aforesaid recommendation of the committee, and information concerning such provisions and effective time has been disseminated among handlers of such oranges; it is necessary, in order to effectuate the declared policy of the act, to make this section effective during the period hereinafter set forth so as to provide for the continued regulation of the handling of oranges, including Temple oranges, and compliance with this section will not require any special preparation on the part of the persons subject thereto which cannot be completed by the effective time hereof.

(b) *Order.* (1) Terms used in the amended marketing agreement and order shall, when used herein, have the same meaning as is given to the respective term in said amended marketing agreement and order; and terms relating to grade, diameter, standard pack, and standard box, as used herein, shall have the same meaning as is given to the respective term in the United States Standards for Florida Oranges and Tangelos (§§ 51.1140–51.1178 of this title).

(2) During the period beginning at 12:01 a.m., e.s.t., October 19, 1964, and ending at 12:01 a.m., e.s.t., November 16, 1964, no handler shall ship between the production area and any point outside thereof in the continental United States, Canada, or Mexico:

(i) Any oranges, except Temple oranges, grown in the production area, which do not grade at least U.S. No. 1;

(ii) Any oranges, except Temple oranges, grown in the production area, which are of a size smaller than 2$^{9}/_{16}$ inches in diameter, except that a tolerance of 10 percent, by count, of oranges smaller than such minimum diameter shall be permitted, which tolerance shall be applied in accordance with the provisions for the application of tolerances specified in said United States Standards for Florida Oranges and Tangelos: *Provided,* That in determining the percentage of oranges in any lot which are smaller than 2$^{9}/_{16}$ inches in diameter, such percentage shall be based only on those oranges in such lot which are of a size 2$^{15}/_{16}$ inches in diameter or smaller;

(iii) Any Temple oranges, grown in the production area, which do not grade at least U.S. No. 1 Russet; or

(iv) Any Temple oranges, grown in the production area, which are of a size smaller than 2$^{9}/_{16}$ inches in diameter, except that a tolerance of 10 percent, by count, of Temple oranges smaller than such minimum diameter shall be permitted which tolerance shall be applied in accordance with the provisions for the application of tolerances specified in the aforesaid United States Standards for Florida Oranges and Tangelos.

(Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674)

Dated: October 15, 1964.

PAUL A. NICHOLSON,
Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[F.R. Doc. 64–10654; Filed, Oct. 16, 1964; 8:50 a.m.]

[Grapefruit Reg. 42]

PART 905—ORANGES, GRAPEFRUIT, TANGERINES, AND TANGELOS GROWN IN FLORIDA

Limitation of Shipments

§ 905.427 Grapefruit Regulation 42.

(a) *Findings.* (1) Pursuant to the marketing agreement, as amended, and Order No. 905, as amended (7 CFR Part 905), regulating the handling of oranges, grapefruit, tangerines, and tangelos grown in Florida, effective under the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), and upon the basis of the recommendations of the committees established under the aforesaid amended marketing agreement and order, and upon other available information, it is hereby found that the limitation of shipments of grapefruit, as hereinafter provided, will tend to effectuate the declared policy of the act.

(2) It is hereby further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rule making procedure, and postpone the effective date of this section until 30 days after publication thereof in the FEDERAL REGISTER (5 U.S.C. 1001–1011) because the time intervening between the date when information upon which this section is based became available and the time when this section must become effective in order to effectuate the declared policy of the act is in-

sufficient; a reasonable time is permitted under the circumstances, for preparation for such effective time; and good cause exists for making the provisions hereof effective as hereinafter set forth. Shipments of all grapefruit, grown in the production area, are presently subject to regulation by grades and sizes, pursuant to the amended marketing agreement and order; the recommendation and supporting information for regulation during the period specified herein were promptly submitted to the Department after an open meeting of the Growers Administrative Committee on October 13, 1964, such meeting was held to consider recommendations for regulation, after giving due notice of such meeting, and interested persons were afforded an opportunity to submit their views at this meeting; the provisions of this section, including the effective time hereof, are identical with the aforesaid recommendation of the committee, and information concerning such provisions and effective time has been disseminated among handlers of such grapefruit; it is necessary, in order to effectuate the declared policy of the act, to make this section effective during the period hereinafter set forth so as to provide for the continued regulation of the handling of grapefruit, and compliance with this section will not require any special preparation on the part of the persons subject thereto which cannot be completed by the effective time hereof.

(b) *Order.* (1) Terms used in the amended marketing agreement and order shall, when used herein, have the same meaning as is given to the respective term in said amended marketing agreement and order; and terms relating to grade, diameter, standard pack, and standard box, as used herein, shall have the same meaning as is given to the respective term in the United States Standards for Florida Grapefruit (§§ 51.750–51.783 of this title).

(2) During the period beginning at 12:01 a.m., e.s.t., October 19, 1964, and ending at 12:01 a.m., e.s.t., November 16, 1964, no handler shall ship between the production area and any point outside thereof in the continental United States, Canada, or Mexico:

(i) Any seeded grapefruit, grown in the production area, which do not grade at least U.S. No. 1;

(ii) Any seeded grapefruit, grown in the production area, which are smaller than $3\frac{15}{16}$ inches in diameter, except that a tolerance of 10 percent, by count, of seeded grapefruit smaller than such minimum size shall be permitted, which tolerance shall be applied in accordance with the provisions for the application of tolerances, specified in said United States Standards for Florida Grapefruit;

(iii) Any seedless grapefruit, grown in Regulation Area I, which do not grade at least U.S. No. 1;

(iv) Any seedless grapefruit, grown in Regulation Area II, which do not grade at least U.S. No. 1 Russet: *Provided,* That such grapefruit which grade U.S. No. 2 or U.S. No. 2 Bright, may be shipped if such grapefruit meet the requirements as to form (shape) and color specified in the U.S. No. 1 grade; or

(v) Any seedless grapefruit grown in the production area, which are smaller than $3\frac{9}{16}$ inches in diameter, except that a tolerance of 10 percent, by count, of seedless grapefruit smaller than such minimum size shall be permitted, which tolerance shall be applied in accordance with the provisions for the application of tolerances, specified in said United States Standards for Florida grapefruit.

(Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674)

Dated: October 15, 1964.

PAUL A. NICHOLSON,
Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[F.R. Doc. 64–10655; Filed, Oct. 16, 1964; 8:50 a.m.]

[Lemon Reg. 133]

PART 910—LEMONS GROWN IN CALIFORNIA AND ARIZONA

Limitation of Handling

§ 910.433 **Lemon Regulation 133.**

(a) *Findings.* (1) Pursuant to the marketing agreement, as amended, and Order No. 910, as amended (7 CFR Part 910; 27 F.R. 8346), regulating the handling of lemons grown in California and Arizona, effective under the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), and upon the basis of the recommendation and information submitted by the Lemon Administrative Committee, established under the said amended marketing agreement and order, and upon other available information, it is hereby found that the limitation of handling of such lemons as hereinafter provided will tend to effectuate the declared policy of the act.

(2) It is hereby further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rule making procedure, and postpone the effective date of this section until 30 days after publication hereof in the FEDERAL REGISTER (5 U.S.C. 1001–1011) because the time intervening between the date when information upon which this section is based became available and the time when this section must become effective in order to effectuate the declared policy of the act is insufficient, and a reasonable time is permitted, under the circumstances, for preparation for such effective time; and good cause exists for making the provisions hereof effective as hereinafter set forth. The committee held an open meeting during the current week, after giving due notice thereof, to consider supply and market conditions for lemons and the need for regulation; interested persons were afforded an opportunity to submit information and views at this meeting; the recommendation and supporting information for regulation during the period specified herein were promptly submitted to the Department after such meeting was held; the provisions of this section, including its effective time, are identical with the aforesaid recommendation of the committee, and information concerning such provisions and effective time has been disseminated among handlers of such lemons; it is necessary, in order to effectuate the declared policy of the act, to make this section effective during the period herein specified; and compliance with this section will not require any special preparation on the part of persons subject hereto which cannot be completed on or before the effective date hereof. Such committee meeting was held on October 13, 1964.

(b) *Order.* (1) The respective quantities of lemons grown in California and Arizona which may be handled during the period beginning at 12:01 a.m., P.s.t., October 18, 1964, and ending at 12:01 a.m., P.s.t., October 25, 1964, are hereby fixed as follows:

(i) District 1: Unlimited movement;
(ii) District 2: 106,950 cartons;
(iii) District 3: 106,950 cartons.

(2) As used in this section, "handled," "District 1," "District 2," "District 3," and "carton" have the same meaning as when used in the said amended marketing agreement and order.

(Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674)

Dated: October 15, 1964.

PAUL A. NICHOLSON,
Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[F.R. Doc. 64–10675; Filed, Oct. 16, 1964; 8:50 a.m.]

[Area 1]

PART 948—IRISH POTATOES GROWN IN COLORADO

Limitation of Shipments

Findings. (a) Pursuant to Marketing Agreement No. 97, as amended, and Order No. 948, as amended (7 CFR Part 948), regulating the handling of Iirsh potatoes grown in Colorado, effective under the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 et seq.), and upon the basis of recommendations and information submitted by the Area No. 1 Committee, established pursuant to the said marketing agreement and order, and other available information, it is hereby found that the limitation of shipments, hereinafter set forth, will tend to maintain orderly marketing conditions and increase returns to producers of such potatoes.

(b) It is hereby found that it is impracticable and contrary to the public interest to give preliminary notice or engage in public rule making procedure, and that good cause exists for not postponing the effective date of this section until 30 days after publication in the FEDERAL REGISTER (5 U.S.C. 1003) in that (1) shipments of 1964 crop potatoes grown in Area No. 1 have begun, (2) to maximize benefits to producers, this regulation should be made effective as soon as practicable, (3) producers and handlers have operated under the said marketing order program since 1949 so special preparation on the part of handlers

is not required, and (4) information regarding the committee's recommendation has been disseminated to producers and handlers in the production area.

§ 948.347 Limitation of shipments.

During the period from October 19, 1964, through June 30, 1965, no person shall handle any lot of potatoes grown in Area No. 1 unless such potatoes meet the requirements of paragraphs (a) and (b) of this section, or unless such potatoes are handled in accordance with the provisions of paragraphs (c), (d), and (e) of this section.

(a) *Minimum grade and size requirements*—(1) *Round varieties.* U.S. No. 2, or better grade, 2 inches minimum diameter.

(2) *Long varieties.* U.S. No. 2, or better grade, 1⅞ inches minimum diameter.

(3) *All varieties.* Size B, if U.S. No. 1 or better grade.

(b) *Minimum maturity (skinning) requirements*—(1) *All varieties.* Not more than "moderately skinned."

(c) *Special purpose shipments.* (1) The quality and maturity requirements set forth in paragraphs (a) and (b) of this section and the inspection and assessment requirements of this part shall not be applicable to potatoes handled for livestock feed.

(2) Potatoes may be handled for chipping or shoestrings if such potatoes meet the grade and size requirements of paragraph (a) of this section except for scab. The maturity requirements of paragraph (b) of this section shall not apply to such potatoes handled for chipping or shoestrings.

(3) The quality and maturity requirements of paragraphs (a) and (b) of this section shall not be applicable to the handling of potatoes for seed as defined in § 948.6 but any lot of potatoes handled for seed shall be subject to assessments.

(d) *Safeguards.* (1) Each handler of potatoes which do not meet the quality or maturity requirements of paragraphs (a) and (b) of this section and which are handled pursuant to paragraph (c) of this section for any of the special purposes set forth therein shall, prior to handling, apply for and obtain a Certificate of Privilege from the committee, which shall require among other things, the handler to furnish such reports and documents as the committee may require showing that the potatoes so handled were utilized for the purpose specified in the Certificate of Privilege.

(e) *Exception to regulations.* The requirements of this part shall not apply to the handling of potatoes grown in the Counties of Dolores, La Plata and Montezuma during the effective period of this section.

(f) *Definitions.* The terms "U.S. No. 1," "U.S. No. 2," "moderately skinned," "scab" and "Size B" shall have the same meaning as when used in the United States Standards for Potatoes (§§ 51.1540–51.1556 of this title), including the tolerances set forth therein. Other terms used in this section shall have the same meaning as when used in Marketing Agreement No. 97, as amended, and this part.

(Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601 et seq.)

Dated October 14, 1964, to become effective October 19, 1964.

PAUL A. NICHOLSON,
Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[F.R. Doc. 64–10620; Filed, Oct. 16, 1964; 8:47 a.m.]

Title 9—ANIMALS AND ANIMAL PRODUCTS

Chapter I—Agricultural Research Service, Department of Agriculture

SUBCHAPTER C—INTERSTATE TRANSPORTATION OF ANIMALS AND POULTRY

PART 74—SCABIES IN SHEEP

Permitted Dips; Substances Allowed

Pursuant to the provisions of sections 1 and 3 of the Act of March 3, 1905, as amended, sections 1 and 2 of the Act of February 2, 1903, as amended, and sections 4 and 5 of the Act of May 29, 1884, as amended (21 U.S.C. 111–113, 120, 121, 123, 125), § 74.24 of Part 74, Title 9, Code of Federal Regulations, as amended, containing the regulations restricting the interstate movement of sheep because of scabies is hereby amended in the following respects:

A new subparagraph (3) is added to paragraph (a) and paragraphs (b) and (c) of § 74.24 are amended to read as follows:

§ 74.24 Permitted dips; substances allowed.

(a) * * *

(3) Dip made from specifically permitted proprietary brands of wettable powders containing 25 percent lindane (gamma isomer of benzene hexachloride) as the active ingredient and maintained throughout the dipping operation at a concentration between 0.05 and 0.06 percent. Animals treated with such dip should not be slaughtered for food purposes until the expiration of such period as may be required under the Meat Inspection Act (21 U.S.C. 71 et seq.). The length of this required period shall be specified on each certificate issued by the Division or State inspector or accredited veterinarian who supervises the dipping with such dip.

* * * * *

(b) Proprietary brands of toxaphene, lindane, lime-sulphur, or nicotine dips may be used in official dipping only after specific permission therefor has been issued by the Division.[2]

(c) The dipping bath for the lime-sulphur and nicotine dips must be used at a temperature of 95° to 105° F., and must be maintained at all times at a strength of not less than 1½ percent of "sulphide sulphur" in the case of the lime-sulphur dip, and not less than five one-hundredths of 1 percent of nicotine in the case of the nicotine dip, as indicated by the field tests for such baths approved by the Division.[3] The dipping bath for toxaphene emulsions must be kept within a temperature range of 40°–80° F., and at a concentration between 0.5 and 0.6 percent during dipping operations.[4] The dipping bath for lindane wettable powders must be constantly agitated by means of compressed air injected along the bottom and sides of the vat from a suitable air compressor that delivers sufficient air volume to cause bubbling of the vat contents along the entire length of the vat. The air compressor shall be connected by means of a hose or other satisfactory plumbing connections to a 1¼-inch pipe containing two rows of holes directed downward and outward. The holes shall be 1/16 inch in diameter and be spaced on 5-inch centers, and the pipe shall be situated along the center of the vat floor extending the entire length of the lowermost portion of the vat.

* * * * *

(Secs. 4, 5, 23 Stat. 32, as amended, secs. 1, 2, 32 Stat. 791–792, as amended, secs. 1, 3, 33 Stat. 1264, as amended, 1265, as amended; 21 U.S.C. 111–113, 120, 121, 123, 125. Interpret or apply secs. 6, 7, 23 Stat. 32, as amended, secs. 2, 4, 33 Stat. 1264, as amended, 1265, as amended; 21 U.S.C. 115, 117, 124, 126; 19 F.R. 74, as amended)

Effective date. The amendments shall become effective upon publication in the FEDERAL REGISTER.

The purpose of the amendments is to provide for the use of permitted proprietary brands of lindane wettable powders, which may be used under the regulations relating to scabies in sheep where dipping of such animals in a permitted dip is required prior to interstate movement.

The amendments must be made effective promptly in order to be of maximum benefit in preventing the spread of scabies in sheep. Accordingly, under section 4 of the Administrative Procedure Act (5 U.S.C. 1003), it is found upon good cause that notice and other public procedure with respect to the amendments are impracticable and contrary to the public interest, and good cause is found for making the amendments effective less than 30 days after publication in the FEDERAL REGISTER.

Done at Washington, D.C., this 13th day of October 1964.

B. T. SHAW,
Administrator, Agricultural Research Service.

[F.R. Doc. 64–10641; Filed, Oct. 16, 1964; 8:49 a.m.]

[2] Names of such brands may be obtained from the Division or a Division inspector.

[3] The field test for lime-sulphur dipping baths is described in U.S. Department of Agriculture Bulletin 163, for sale by the Superintendent of Documents, Government Printing Office, Washington 25, D.C., at 5 cents a copy. A field test outfit at present approved by the Division for nicotine-dipping baths is that designated for the purpose of identification as "Field test outfit N–3." (Description available on application to the Department.)

[4] Care must be exercised in dipping animals and in maintaining the bath at the standard concentration when using any permitted dip. Detailed instructions will be issued for the guidance of employees who may be called upon to to use them in the scabies eradication program.

Title 14—AERONAUTICS AND SPACE

Chapter I—Federal Aviation Agency

[Airspace Docket No. 64-SO-17]

PART 71—DESIGNATION OF FEDERAL AIRWAYS, CONTROLLED AIRSPACE, AND REPORTING POINTS [NEW]

Alteration of Federal Airway

On August 20, 1964, a notice of proposed rule making was published in the FEDERAL REGISTER (29 F.R. 11926) stating that the Federal Aviation Agency proposed to realign the segment of VOR Federal airway No. 176 from Holly Springs, Miss., to Birmingham, Ala., via a new VOR to be commissioned in the vicinity of Hamilton, Ala., on November 12, 1964. In addition, it was proposed to redesignate the Hamilton intersection reporting point at the Hamilton VOR.

Interested persons were afforded an opportunity to participate in the rule making through submission of comments. All comments received were favorable.

In consideration of the foregoing Part 71 of the Federal Aviation Regulations is amended, effective 0001 e.s.t., December 10, 1964, as hereinafter set forth.

1. In § 71.123 (29 F.R. 1009) V-176 is amended to read:

V-176 From Memphis, Tenn., via Holly Springs, Miss., including a S alternate via INT of Memphis 168° and Holly Springs 281° radials; Hamilton, Ala.; to Birmingham, Ala., including a N alternate from Holly Springs to Birmingham via INT of Holly Springs 099° and Birmingham 313° radials.

2. In § 71.203 (29 F.R. 1211) "Hamilton INT: INT Birmingham, Ala., 298°, Columbus, Miss., 035° radials." is deleted and "Hamilton, Ala." is substituted therefor.

(Sec. 307(a), Federal Aviation Act of 1958; 49 U.S.C. 1348)

Issued in Washington, D.C. on October 13, 1964.

H. B. HELSTROM,
Acting Chief, Airspace Regulations and Procedures Division.

[F.R. Doc. 64-10606; Filed, Oct. 16, 1964; 8:45 a.m.]

[Airspace Docket No. 64-WA-63]

PART 71—DESIGNATION OF FEDERAL AIRWAYS, CONTROLLED AIRSPACE, AND REPORTING POINTS [NEW]

Alteration of Federal Airway

On September 23, 1964, Federal Register Document No. 64-9606 was published in the FEDERAL REGISTER (29 F.R. 13164) amending Part 71 [New] of the Federal Aviation Regulations. These amendments realigned VOR Federal airway No. 318 from Houlton, Maine, to a new VOR to be commissioned at Quebec, Canada, and extended VOR Federal airway No. 447 from Montpelier, Vt., to the United States/Canadian border toward the Sherbrooke, Canada VOR, effective November 19, 1964.

The Agency has been informed by the Canadian Department of Transport that, because of technical difficulties, the Quebec VOR will not be commissioned in the near future.

For the above reason it has been determined that compliance with the notice and public procedure requirements of the Administrative Procedure Act is impracticable and contrary to the public interest, and for this reason good cause exists for making this amendment effective within less than 30 days from the date of publication in the FEDERAL REGISTER.

In consideration of the foregoing, effective immediately, the text of the amendment in Federal Register Document No. 64-9606 is amended to read as follows:

In § 71.123 (29 F.R. 1009, 9529) V-447 is amended to read:

V-447 From Montpelier, Vt., via the INT of Montpelier 020° and Sherbrooke, P.Q., Canada, 217° radials; to Sherbrooke. The portion within Canada is excluded.

(Sec. 307(a), Federal Aviation Act of 1958; 49 U.S.C. 1348)

Issued in Washington, D.C., on October 13, 1964.

H. B. HELSTROM,
Acting Chief, Airspace Regulations and Procedures Division.

[F.R. Doc. 64-10607; Filed, Oct. 16, 1964; 8:45 a.m.]

[Airspace Docket No. 62-AL-11]

PART 71—DESIGNATION OF FEDERAL AIRWAYS, CONTROLLED AIRSPACE, AND REPORTING POINTS [NEW]

Designation of Federal Airway Segment

On January 17, 1963, a notice of proposed rule making was published in the FEDERAL REGISTER (28 F.R. 455) stating that the Federal Aviation Agency proposed to designate a VOR Federal airway segment from Fairbanks, Alaska, via Eielson AFB, Alaska, to Big Delta, Alaska. On July 28, 1964, a supplemental notice of proposed rule making was published in the FEDERAL REGISTER (29 F.R. 10472) which altered the proposal in the original notice by stating that the proposed airway segment would be designated from Big Delta direct to the intersection of the Big Delta 313° and the Nenana, Alaska, 064° True radials (Fairbanks ILS LMM).

Interested persons were afforded an opportunity to participate in the rule making through submission of comments; however, no comments were received.

Although not mentioned in the notice or the supplemental notice, it has been determined that the Big Delta VOR should be designated as a low altitude reporting point for air traffic control purposes. Accordingly, action is taken herein to designate the Big Delta reporting point.

Since this action is minor in nature and will impose no additional burden on any person, notice and public procedure requirements hereon are unnecessary.

In consideration of the foregoing, Part 71 [New] of the Federal Aviation Regulations is amended, effective 0001 e.s.t., December 10, 1964, as hereinafter set forth.

1. Section 71.125 (29 F.R. 1046, 9663) is amended as follows: In V-444 "From Big Delta, Alaska," is deleted and "From INT Big Delta, Alaska, 313° and Nenana, Alaska, 064° radials (Fairbanks ILS LMN), via Big Delta;" is substituted therefor.

2. In § 71.211 (29 F.R. 1228) add "Big Delta, Alaska."

(Sec. 307(a), Federal Aviation Act of 1958; 49 U.S.C. 1348)

Issued in Washington, D.C., on October 12, 1964.

D. E. BARROW,
Chief, Airspace Regulations and Procedures Division.

[F.R. Doc. 64-10605; Filed, Oct. 16, 1964; 8:45 a.m.]

[Airspace Docket No. 63-SW-106]

PART 71—DESIGNATION OF FEDERAL AIRWAYS, CONTROLLED AIRSPACE, AND REPORTING POINTS [NEW]

Designation of Control Zone and Transition Area

On August 15, 1964, a notice of proposed rule making was published in the FEDERAL REGISTER (29 F.R. 11720) stating that the Federal Aviation Agency proposed to designate a control zone and transition area at Fort Polk, La.

Interested persons were afforded an opportunity to participate in the rule making through submission of comments. All comments received were favorable.

In consideration of the foregoing, Part 71 [New] of the Federal Aviation Regulations is amended, effective 0001 e.s.t., December 10, 1964, as hereinafter set forth.

1. § 71.171 (29 F.R. 1101) is amended by designating the Fort Polk, La., control zone as follows:

Fort Polk, La.

Within a 5-mile radius of Polk AAF (latitude 31°02'40" N., longitude 93°11'25" W.); within 2 miles each side of the 160° bearing from the Polk RBn, extending from the 5-mile radius zone to 8 miles SE of the RBn, within 2 miles each side of the 340° bearing from the RBn, extending from the 5-mile radius zone to 8 miles NW of the RBn; excluding the portion within R-3804A. This control zone is effective from 0730 to 1630 hours, local time, Monday through Friday, and from 0730 to 1130 hours, local time, Saturday.

2. Section 71.181 (29 F.R. 1160) is amended by designating the Fort Polk, La., transition area as follows:

Fort Polk, La.

That airspace extending upward from 1,200 feet above the surface within 8 miles W and 5 miles E of the 340° and 160° bearings from the Polk RBn, extending from 12 miles SE to 12 miles NW of the RBn, excluding the portion within R-3804A.

(Sec. 307(a), Federal Aviation Act of 1958; 49 U.S.C. 1348)

Issued in Washington, D.C., on October 12, 1964.

H. B. HELSTROM,
Acting Chief, Airspace Regulations and Procedures Division.

[F.R. Doc. 64-10603; Filed, Oct. 16, 1964; 8:45 a.m.]

[Airspace Docket No. 64-WE-14]

PART 71—DESIGNATION OF FEDERAL AIRWAYS, CONTROLLED AIRSPACE, AND REPORTING POINTS [NEW]

Designation of Control Zone

On August 6, 1964, a notice of proposed rule making was published in the FEDERAL REGISTER (29 F.R. 11383) stating that the Federal Aviation Agency proposed to designate a part time control zone at Lake Tahoe, Calif.

Interested persons were afforded an opportunity to participate in the rule making through submission of comments. All comments received were favorable.

In consideration of the foregoing, Part 71 [New] of the Federal Aviation Regulations is amended, effective 0001 e.s.t. December 10, 1964, as hereinafter set forth.

In § 71.171 (29 F.R. 1101), the following is added:

Lake Tahoe, Calif.

Within a 5-mile radius of Lake Tahoe Airport (latitude 38°53'30" N., longitude 119°59'50" W.), effective from 0700 to 2300 hours, local time, daily.

(Sec. 307(a), Federal Aviation Act of 1958; 49 U.S.C. 1348)

Issued in Washington, D.C., on October 13, 1964.

H. B. HELSTROM,
Acting Chief, Airspace Regulations and Procedures Division.

[F.R. Doc. 64-10604; Filed, Oct. 16, 1964; 8:45 a.m.]

[Airspace Docket No. 63-WE-123]

PART 71—DESIGNATION OF FEDERAL AIRWAYS, CONTROLLED AIRSPACE, AND REPORTING POINTS [NEW]

Alteration of Transition Area and Federal Airway; Designation of Control Zone and Federal Airway

On August 1, 1964, a notice of proposed rule making was published in the FEDERAL REGISTER (29 F.R. 11163) stating that the Federal Aviation Agency proposed to alter the controlled airspace in the Durango, Colo., terminal area and establish VOR Federal airways to and from Durango.

Interested persons were afforded an opportunity to participate in the rule making through submission of comments. All comments received were favorable.

In consideration of the foregoing, Part 71 [New] of the Federal Aviation Regulations is amended, effective 0001 e.s.t., December 10, 1964, as hereinafter set forth.

(a) In § 71.171 (29 F.R. 1101) the following is added:

Durango, Colo.

Within a 5-mile radius of La Plata Field (latitude 37°09'15" N., longitude 107°45'00" W.), effective from 0600 to 2200 hours local time, daily.

(b) In § 71.181 (29 F.R. 1160) the Durango, Colo., transition area is amended to read:

Durango, Colo.

That airspace extending upward from 700 feet above the surface within a 5-mile radius of La Plata Field (latitude 37°09'15" N., longitude 107°45'00" W.), and within 2 miles SW and 3 miles NE of the Durango VOR 118° radial, extending from the 5-mile radius area to 8 miles SE of the VOR; and that airspace extending upward from 1,200 feet above the surface, within 9 miles SW and 6 miles NE of the Durango VOR 298° and 118° radials, extending from 7 miles NW to 14 miles SE of the VOR.

(c) Section 71.123 (29 F.R. 1009, 5540) is amended as follows:

(1) V-421 is amended to read:

V-421 From Zuni, N. Mex., via Farmington, N. Mex.; Durango, Colo.; to Gunnison, Colo., excluding the airspace below 1,200 feet above the surface from Farmington to Gunnison.

(2) V-211 is added as follows:

V-211 From INT Alamoso, Colo., 232° and Durango, Colo., 110° radials via Durango; to INT Durango 284° and Dove Creek, Colo., 147° radials, excluding the airspace below 1,200 feet above the surface.

(Sec. 307(a), Federal Aviation Act of 1958; 49 U.S.C. 1348)

Issued in Washington, D.C., on October 13, 1964.

H. B. HELSTROM,
Acting Chief, Airspace Regulations and Procedures Division.

[F.R. Doc. 64-10608; Filed, Oct. 16, 1964; 8:46 a.m.]

[Airspace Docket No. 63-EA-51]

PART 71—DESIGNATION OF FEDERAL AIRWAYS, CONTROLLED AIRSPACE, AND REPORTING POINTS [NEW]

PART 75—ESTABLISHMENT OF JET ROUTES [NEW]

Alteration of Control Area and Jet Routes

On August 1, 1964, a notice of proposed rule making was published in the FEDERAL REGISTER (29 F.R. 11162) stating that the Federal Aviation Agency was considering amendments to Parts 71 and 75 [new] of the Federal Aviation Regulations, that would alter the United States portion of Control 1141, Boston, Mass., to Yarmouth, N.S., Canada; extend Jet Route No. 62 from Nantucket, Mass., to the United States/Canadian border toward Yarmouth and establish Jet Route No. 575 from Boston to the United States/Canadian border toward Yarmouth.

Interested persons were afforded an opportunity to participate in the rule making through submission of comments. Due consideration was given to all relevant matter presented.

The Air Transport Association of America endorsed the proposals. The Department of the Navy offered no objection to the proposals provided alterations to Warning Areas W-102, W-103, and W-104 as proposed in Eastern Region Case No. EA-465-NR, dated June 7, 1963, and amended January 7, 1964, are consummated. These nonrule-making actions will be taken concurrently with the actions taken herein.

The proposals contained herein have been coordinated with the Canadian Department of Transport.

Subsequent to publication of the Notice, Jet Route No. 575 was designated from Kennedy, N.Y., to Boston, Mass., effective October 15, 1964 (Airspace Docket No. 63-EA-103, 29 F.R. 12362). Accordingly, action is taken herein to extend J-575 from Boston to the United States/Canadian border toward Yarmouth. In addition, the Canadian Department of Transport has requested that the segment of Jet Route No. 62 as proposed for alteration herein, be numbered Jet Route No. 585 to join Canadain High Level airway No. 585. Such action is taken herein.

In consideration of the foregoing, Part 71 [New] and Part 75 [New] of the Federal Aviation Regulations are amended, effective 0001 e.s.t. December 10, 1964, as hereinafter set forth.

1. In § 71.163 (29 F.R. 1068) Control 1141 is amended to read:

Control 1141

That airspace within tangent lines from the circumference of a 5-mile radius circle centered on the Boston, Mass., radio beacon to a 15-mile radius circle centered on the midway point of a direct line between the Boston radio beacon and the Yarmouth, Nova Scotia, Canada, RR to a 5-mile radius circle centered on the Yarmouth RR and that airspace from 18,000 feet MSL to flight level 260 bounded by a line from: latitude 42°43'20" N., longitude 70°22'00" N., thence to latitude 42°52'00" N., longitude 70°16'00" W.; thence to latitude 43°01'30" N., longitude 69°52'00" W.; thence to latitude 43°01'30" N., longitude 69°36'00" W.; thence to the point of beginning; and that airspace from 18,000 feet MSL to flight level 260 inclusive bounded by a line from: latitude 42°33'35" N., longitude 70°03'45" W.; thence to latitude 42°42'30" N., longitude 69°30'00" N.; thence to latitude 42°39'00" N., longitude 69°30'00" W.; thence to latitude 42°28'00" N., longitude 70°03'45" W.; thence to the point of beginning excluding the portion under the jurisdiction of Canada, the portion within the confines of Federal airways and the Boston, Mass., control area extension, the portion below 2,000 feet MSL W of the 69°30'00" W. meridian of longitude and the portion below 5,500 feet MSL E of the 69°30'00" W. meridian of longitude.

2. In § 75.100 (29 F.R. 1287, 12362) the following changes are made:

a. Jet Route No. 575 is amended to read:

Jet Route No. 575 (Kennedy, N.Y., to Yarmouth, N.S., Canada). (Joins Canadian high level airway No. 575).

From Kennedy, N.Y., via Boston, Mass.; to Yarmouth, N.S., Canada, excluding the portion under the jurisdiction of Canada.

b. Jet Route No. 585 is added as follows:

Jet Route No. 585 (Nantucket, Mass., to Yarmouth, N.S., Canada). (Joins Canadian high level airway No. 585).

From Nantucket, Mass., to Yarmouth, N.S., Canada, excluding the portion under the jurisdiction of Canada.

(Secs. 307(a), E.O. 1110, Federal Aviation Act of 1958; 49 U.S.C. 1348 and 1510; 10854, 24 F.R. 9565)

Issued in Washington, D.C., on October 13, 1964.

H. B. HELSTROM,
Acting Chief, Airspace Regulations and Procedures Division.

[F.R. Doc. 64-10602; Filed, Oct. 16, 1964; 8:45 a.m.]

Title 25—INDIANS

Chapter I—Bureau of Indian Affairs, Department of the Interior

SUBCHAPTER F—ENROLLMENT

PART 43a—MEMBERSHIP ROLL OF PONCA TRIBE OF NATIVE AMERICANS OF NEBRASKA

Miscellaneous Amendments

On page 11925 of the FEDERAL REGISTER of August 20, 1964, there was published a notice and text of a proposed amendment to §§ 43a.1, 43a.3, 43a.5, and 43a.11 of Title 25 Code of Federal Regulations. The purpose of the amendment is to conform certain language in the regulations to the language used in the Act of September 5, 1962 (76 Stat. 429), regarding reference to blood degree of the Ponca Tribe of Native Americans of Nebraska, and to more fully reflect the intent of the Congress as to Indians eligible to enroll as members of the Tribe.

Interested persons were given 30 days within which to submit written comments, suggestions, or objections with respect to the proposed amendment. No comments, suggestions, or objections were received, and the proposed amendment is hereby adopted without change and is set forth below. Because the amendment relieves a restriction on certain potential members of the Ponca Tribe of Native Americans of Nebraska, it shall become effective on the date of this publication in the FEDERAL REGISTER.

JOHN A. CARVER, JR.,
Assistant Secretary of the Interior.

OCTOBER 9, 1964.

1. Section 43a.1(i) is amended to include all descendants of enrolled members in the definition for "descendants." As so amended, § 43a.1(i) reads as follows:

§ 43a.1 Definitions.

As used in this Part 43a:

* * * * *

(i) "Descendants" means those persons who have issued from an enrollee and include the enrollee's children, grandchildren, and so on, who possess at least one-fourth degree of Indian blood of the Ponca Tribe.

* * * * *

2. Sections 43a.3(a) (1) and (2) are amended to further define eligibility for enrollment more fully reflecting the intent of the Congress in the Act, supra. As so amended, § 43a.3(a) (1) and (2) read as follows:

§ 43a.3 Eligibility for enrollment.

(a) The following shall be eligible for enrollment:

(1) Those persons whose names appear on the census roll of April 1, 1934, and the January 1, 1935, supplement thereto, or are entitled to appear thereon, and who were living on September 5, 1962.

(2) Descendants, regardless of residence, who were living on September 5, 1962, and who possess not less than one-fourth degree of Indian blood of the Ponca Tribe. All available records will be used in determining degree of Indian blood of the Ponca Tribe possessed by descendants.

* * * * *

3. Section 43a.5(b) (2) is amended to conform the wording in reference to Indian blood to the wording of the Act, supra. As so amended, § 43a.5(b) (2) reads as follows:

* * * * *

§ 43a.5 Application forms.

* * * * *

(b) Among other information, each application requires:

* * * * *

(2) Degree of Indian blood of the Ponca Tribe.

* * * * *

4. Section 43a.11(a) is amended for the same purpose as shown in Item 3, above. As so amended, § 43a.11(a) reads as follows:

§ 43a.11 Preparation of final roll.

(a) When final determinations have been made by the Secretary on all appeals, the Commissioner shall prepare a final roll of the tribe. The final roll shall contain for each person the final roll number, proposed roll number, name, address, sex, date of birth, and degree of Indian blood of the Ponca Tribe. There shall also be provided a "remarks" column for the purpose of identifying the enrollee through whom enrollment rights were established.

* * * * *

[F.R. Doc. 64-10611; Filed, Oct. 16, 1964; 8:46 a.m.]

SUBCHAPTER G—TRIBAL GOVERNMENT

PART 52—TRIBES ORGANIZED UNDER SECTION 16 OF THE INDIAN REORGANIZATION ACT

On page 6545 of the FEDERAL REGISTER of June 26, 1963, there was published a notice and text of the proposed addition of Part 52 to Title 25, Code of Federal Regulations. The purpose of Part 52 is to provide uniformity and order in holding elections on tribal constitutions and bylaws and constitutional amendments, except in Oklahoma and Alaska, and to facilitate the calling of such elections by the Secretary under the provisions of the Indian Reorganization Act.

Interested persons were given 30 days within which to submit written comments, suggestions, or objections with respect to the proposed regulations. As a result of comments received within the 30-day period, which were carefully considered, the proposed regulations are hereby adopted with the following changes and are set forth below:

1. The definition of "Indian", paragraph (d) of § 52.1, has been changed in order that it be more relevant to voting in elections held pursuant to this Part 52.

2. To provide a definition for terms not otherwise defined in the regulations, paragraphs (k) and (l) have been added to § 52.1.

3. In order to clarify the election certification format to be executed by the District Election Board the following insertion has been made in § 52.9 "certification form as prescribed by the Election Board".

4. To assure dissemination of any proposed amendment or constitution, the following has been added to § 52.13. "At any time subsequent to receipt of Secretarial authorization to hold the election, the text of any amendment or proposed constitution shall be made available to the eligible voters of the tribe. The manner and timing of the dissemination shall be within the discretion of the Election Board."

5. To assure that eligible voters of a tribe who are temporarily absent from the reservation are extended the privilege of voting by absentee ballot, the following has been inserted in the second sentence in § 52.17 "temporary absence from reservation," and "an eligible".

6. To clarify the intent of the language "* * * that I will be twenty-one years of age at the election date * * *" as used in the affidavit prescribed in § 52.17, the following has been inserted: "or over".

Part 52 will become effective at the beginning of the 30th calendar day following the date of publication in the FEDERAL REGISTER.

STEWART L. UDALL,
Secretary of the Interior.

OCTOBER 12, 1964.

Part 52, Chapter I, Title 25 of the Code of Federal Regulations reads as follows:

Sec.
52.1 Definitions.
52.2 Purpose and scope.
52.3 Group eligibility.
52.4 Assistance from the Department of the Interior.
52.5 Request to call election.
52.6 Eligibility of voters.
52.7 Adoption by majority vote.
52.8 Election board.
52.9 District election boards.
52.10 Voting districts.
52.11 Voting list.
52.12 Eligibility disputes.
52.13 Election notices.
52.14 Opening and closing of polls.
52.15 Manner of voting.
52.16 Ballots.
52.17 Absentee voting.
52.18 Contesting of election results.

Sec.
52.19 Interpreters.
52.20 Electioneering.
52.21 Certifying election returns.

AUTHORITY: The provisions of this Part 52 issued under 25 U.S.C. 476.

§ 52.1 Definitions.

As used in this Part 52:

(a) "Secretary" means the Secretary of the Interior or his authorized representative.

(b) "Secretarial election" means an election held within a tribe pursuant to regulations prescribed by the Secretary.

(c) "Officer in Charge" means the Superintendent, Administrative Officer, or other official of the local unit of the Bureau of Indian Affairs having jurisdiction.

(d) "Indian" means all persons who are members of, or are eligible for membership in, an Indian tribe under Federal jurisdiction and which tribe has not voted to exclude itself from the Act of June 18, 1934 (48 Stat. 984, as amended, 25 U.S.C. 461, et seq.).

(e) "Adult Indian" means any Indian who has attained the age of 21 years.

(f) "Tribe" means any Indian tribe, organized band, pueblo, or the Indians residing on an Indian reservation or reservations. Such tribes may consist of any consolidation of one or more tribes or parts of tribes.

(g) "Recognized tribe" means any Indian tribe which has entered into a treaty, convention, or executive agreement with the Federal Government or whose tribal entity has been otherwise recognized by the United States.

(h) "Reservation" means any area established by treaty, Federal statute, executive order, or otherwise for the use and occupancy of Indians.

(i) "Indian Reorganization Act" means the Act of June 18, 1934 (48 Stat. 984, as amended, 25 U.S.C. 461, et seq.).

(j) "Constitution," "constitution and bylaws" means the written organizational framework of any organized tribe for the exercise of governmental powers.

(k) "Organized tribe" means a tribe which accepted the Act of June 18, 1934 (48 Stat. 984, as amended, 25 U.S.C. 461, et seq.), and adopted a constitution pursuant to the provisions of the Act, supra.

(l) "Unorganized tribe" means a tribe which, not having voted to exclude itself from the Act of June 18, 1934 (48 Stat. 984, as amended, 25 U.S.C. 461, et seq.), is entitled to organize pursuant to the provisions of the Act, supra, but has not done so.

§ 52.2 Purpose and scope.

The purpose of this Part 52 is to provide uniformity and order in holding elections to vote on constitutions and bylaws and constitutional amendments, and to facilitate the calling of such elections by the Secretary under the provisions of the Indian Reorganization Act.

§ 52.3 Group eligibility.

A constitution and bylaws may be adopted by (a) a tribe or tribes of a reservation, (b) by adult Indian residents of a reservation, or (c) by a traditionally recognized tribe, except that no group which has voted to reject the provisions of the Indian Reorganization Act shall be organized under the Act. A tribe organized under the Indian Reorganization Act shall adopt amendments to its constitution and bylaws under the regulations in this part.

§ 52.4 Assistance from the Department of the Interior.

The Department of the Interior will cooperate with and offer advice and assistance to any eligible group in drafting a constitution and bylaws or an amendment.

§ 52.5 Request to call election.

The Secretary will call an election on adoption of a constitution and bylaws upon request by the Tribal governing body or an authorized representative committee or upon petition filed by at least one-third of the adult members of the group. An election on the adoption of amendments to the constitution and bylaws shall be called by the Secretary when requested as provided in the amendment article of the constitution and bylaws; however, the election shall be conducted in the manner prescribed in the rules and regulations in this part. The Secretary may propose amendments to the constitution for consideration at Secretarial elections, unless the constitution and bylaws for Secretarial elections provide otherwise.

§ 52.6 Eligibility of voters.

(a) If the unorganized group is a tribe or tribes of a reservation.

(1) Any adult member regardless of residence shall be entitled to vote.

(2) Adult nonresidents or ill or physically disabled members may vote by absentee ballot. See § 52.17.

(b) If the unorganized group is composed of the adult Indian residents of a reservation:

(1) Any adult Indian residents shall be entitled to vote.

(2) Absentee voting shall be permitted for residents temporarily absent from the reservation, ill, or physically disabled.

(c) For organized tribes voting in elections for amendments of the constitution and bylaws, only properly eligible voters are entitled to vote, i.e., if the group was organized as a tribe, absentee balloting is permitted, but if the group was organized as residents of a reservation, absentee balloting will not be permitted except as provided in paragraph (b)(2) of this section.

§ 52.7 Adoption by majority vote.

A constitution and bylaws or amendment shall be considered adopted if a majority of those actually voting vote in favor of adoption provided the total vote cast is not less than 30 percent of those entitled to vote; but no action shall become effective until it is approved by the Secretary.

§ 52.8 Election Board.

(a) There shall be an election board consisting of the Officer in Charge acting as chairman and two representatives of an authorized council or committee of Indians. In addition the Officer in Charge may appoint an interpreter and as many clerks and poll watchers as he deems necessary but they shall not be members of the board.

(b) It shall be the duty of the board to conduct elections in compliance with the procedures described in this Part 52 and in particular, (1) to see that the name of each person offering to vote is on the official voting list; (2) to keep the ballot boxes locked at all times except when ballots are being counted; (3) to see that the ballot is cast by the voter himself and that thereupon the voting list is checked to indicate this; (4) as a board to count the regularly cast ballots immediately after the close of the polls, and the absentee ballots immediately after expiration of the time for their receipt; (5) to certify the election returns; (6) to return all the ballots to the ballot boxes which shall be marked and locked together with all unused ballots and a copy of the election returns, to the Officer in Charge.

§ 52.9 District Election Boards.

Where the reservation has been divided into voting districts either by the tribal constitution, ordinance, or resolution, or by the Election Board, the Election Board shall appoint District Election Boards for each district which shall have the duties above prescribed for the Election Board except that it should return the ballots in the ballot boxes, all unused ballots, and its certification (certification form as prescribed by the Election Board) of the district election results to the Election Board which will make the final recapitulation of the election results for the entire reservation and transmit it together with all the aforementioned ballots and ballot boxes to the Officer in Charge.

§ 52.10 Voting districts.

If voting districts have not already been designated and delimited in the tribal constitution or by tribal ordinance or resolution, and in its judgment voting districts throughout the reservation are needed, the Election Board shall delimit them and designate a polling place for each district, taking into consideration the needs and convenience of tribal members.

§ 52.11 Voting list.

The Election Board shall compile an official alphabetical voting list, arranged by voting districts, if any, of the members of the tribe who have attained the age of twenty-one years. A copy of this list shall be supplied to each District Election Board and also posted at the headquarters of the local administrative unit of the Bureau of Indian Affairs and at various public places designated by the Election Board throughout the reservation at least 20 days prior to the election.

§ 52.12 Eligibility disputes.

The Election Board shall determine any written claim to vote presented to it by one whose name is not on the official voting list as well as any written challenge of the right to vote of anyone whose name is on this list, and its decision shall be final. It shall set a date not more than ten nor less than five days before the election to pass on all such matters.

All claims not presented on or before this date shall be automatically disallowed.

§ 52.13 Election notices.

Not less than twenty (20) nor more than sixty (60) days' notice shall be given of an election unless otherwise authorized by the Secretary. If an election is called upon less than twenty (20) days' notice, absentee voters shall nevertheless be allowed twenty (20) days from the giving of such notice for the Election Board to receive their ballots. In such an election the posting of the official voting list shall coincide with the giving of such notice. The Election Board shall determine whether the notice shall be given by television, radio, newspaper, poster or mail, or by one or more of these methods, and whether in an Indian language in addition to English. A copy of any written election notice may be mailed to each voter and posted at the local administrative unit of the Bureau of Indian Affairs and elsewhere as directed by the Election Board. At any time subsequent to receipt of Secretarial authorization to hold the election, the text of any amendment or proposed constitution shall be made available to the eligible voters of the tribe. The manner and timing of the dissemination shall be within the discretion of the Election Board.

§ 52.14 Opening and closing of polls.

The polls shall remain open from 8 a.m. to 7 p.m., local time, unless different hours are set by the Election Board and the voters informed thereof in the election notice.

§ 52.15 Manner of voting.

Any qualified voter may vote by presenting himself at the polls of his voting district within the prescribed voting period, announcing to the officials there his name and address and by marking and placing in the ballot box the ballot which shall be handed to him. Voting shall be by secret ballot. See § 52.17 covering absentee voting.

§ 52.16 Ballots.

The Election Board shall cause to be prepared and furnish all ballots. Each ballot shall be stamped:

OFFICIAL BALLOT
(Facsimile Signature)
CHAIRMAN, ELECTION BOARD

Should any voter spoil or mutilate his ballot in the course of voting, he shall, in the presence of the election officials, and, with their consent, destroy it; the election officials shall then make note of the destroyed ballot and furnish the voter with another ballot.

§ 52.17 Absentee voting.

Nonresident members may vote by absentee ballot except as prohibited by § 52.6(c). Also, whenever due to temporary absence from the reservation, illness, or physical disability an eligible voter is not able to vote at the polls and duly causes the Election Board to be notified thereof, he shall be entitled to vote by absentee ballot. The Election Board shall give or mail ballots for absentee voting to voters upon request in sufficient time to permit the voter to execute and return same on or before the date of the election or within the time allowed by the Election Board. Together with the ballot there shall be an inner envelope bearing on the outside the words "Absentee Ballot," a preaddressed outer envelope, and an affidavit in form as follows:

I, _____, do solemly swear (or affirm) that I am a member of the _____ Tribe of Indians; that I will be twenty-one years of age or over at the election date and am entitled to vote in the election to be held on _____ (Date of election); and that I cannot appear at the polling place on the reservation on the date of the election because (indicate one of the following reasons) I expect to be absent from the reservation ☐ or because of illness ☐ or physical disability ☐. I further swear that I marked the enclosed ballot in secret.

Signed: _____ (Voter)

"Subscribed and sworn to before me this ____ day of _____ 19__; and I hereby certify that the affiant exhibited the ballot to me unmarked; that he then in my presence and in the presence of no other person, and in such manner that I could not see his vote, marked such ballot and enclosed and sealed the same in the envelope marked "Absentee Ballot."

[SEAL] Signed: _____
Title: _____
_____

The voter shall make and subscribe to the affidavit before any officer authorized by law to administer oaths, and thereupon in the presence of such officer and of no other person, mark such ballot but in such manner that such officer cannot know how such ballot was marked, and such ballot shall then in the presence of such officer be folded so as to conceal the marking, and be, in the presence of such officer, placed in the envelope marked "Absentee Ballot" and the envelope sealed. The voter shall then place the sealed envelope marked "Absentee Ballot" together with the affidavit in the outer envelope, and mail it or have it delivered. The preaddressed outer envelope shall be directed to the Election Board at the reservation. Absentee ballots must be received by the Election Board not later than the close of the polls on election day, except as covered by § 52.13. The Election Board shall make and keep a record of ballots mailed, to whom mailed, the date of mailing, the address on the envelope, the date of the return of such ballot, and from whom received, and shall count and register all such votes after all other ballots have been counted and include them in the results of the election.

§ 52.18 Contesting of election results.

Any qualified voter, within three days following the announcement of the results of an election, may challenge the election results by filing with the Secretary through the Officer in Charge his grounds for the challenge, together with substantiating evidence thereof. If in the opinion of the Secretary, the objections are valid and are of a nature to so warrant, the Secretary shall order a recount or a new election. The results of the recount shall be final.

§ 52.19 Interpreters.

Interpreters where needed may be provided to explain the manner of voting to such Indians who ask for instruction provided all reasonable precautions are taken so that the interpreter does not influence the voter in casting his ballot. The interpreter shall not accompany the voter into the booth.

§ 52.20 Electioneering.

There shall be no electioneering during voting hours within 50 feet of any voting place. Sample ballots will be permitted in the voting booth.

§ 52.21 Certifying election returns.

A telegraphic report should be made to the Commissioner of Indian Affairs immediately after the results of the election are determined. The results of the election shall be posted in the Agency Office and at other public places of the reservation. The Election Board shall certify the results of the election on the following form and transmit it to the Bureau:

Certificate of Results of Election. Pursuant to an election authorized by the Secretary of the Interior on _____ (Date), the attached constitution and bylaws, or amendment, of the _____ (Name of organization) was submitted to the qualified voters of the tribe and was on _____ (Date) duly (rejected) (adopted) by a vote of __ for and __ against, in an election in which at least 30 percent of the _____ (Number of members entitled to vote) members entitled to vote cast their ballot in accordance with Section 16 of the Indian Reorganization Act of June 18, 1934 (48 Stat. 984), as amended by the Act of June 15, 1935 (49 Stat. 378). Signed: (By the chairman of the Election Board and the two board members.)

[F.R. Doc. 64-10612; Filed, Oct. 16, 1964; 8:46 a.m.]

Title 26—INTERNAL REVENUE

Chapter I—Internal Revenue Service, Department of the Treasury

SUBCHAPTER E—ALCOHOL, TOBACCO, AND OTHER EXCISE TAXES

[T.D. 6762]

PART 175—TRAFFIC IN CONTAINERS OF DISTILLED SPIRITS

PART 201—DISTILLED SPIRITS PLANTS

Miscellaneous Amendments

On May 5, 1964, a notice of proposed rule making to amend 26 CFR Part 175 was published in the FEDERAL REGISTER (29 F.R. 5905). The purposes of the proposal were to (1) delete the requirement that the words "Federal Law Forbids Sales or Reuse of This Bottle" be marked on liquor bottles; (2) extend the definition of a liquor bottle to include containers of less than one-half pint; (3) exempt liquor bottles of less than one-half pint from indicia requirements; (4) remove any possible implication that

specific bottle sizes are prescribed for liqueurs, cocktails, and certain other specialties; (5) extend existing permit requirements to include liquor bottles of less than one-half pint; (6) permit liquor bottles to be used for display purposes without drilling the bottles or obliterating indicia thereon; (7) permit manufacturers of bottling equipment to secure liquor bottles for use in testing bottling machinery; and (8) reduce the number of photographs required with an application for approval of a distinctive liquor bottle. In accordance with the notice, interested persons were afforded an opportunity to submit written comments or suggestions pertaining thereto. After consideration of all relevant matter presented regarding the proposed amendments, the regulations in 26 CFR Part 175 as so published are hereby adopted, subject to the following changes, and a conforming amendment of the regulations in 26 CFR Part 201 is made as described below:

PARAGRAPH 1. Immediately preceding Paragraph 1, as published in the notice, insert Paragraph A.

PAR. 2. Paragraph 1 of the notice is changed by adding, at the end of § 175.1, a new sentence to read, "The provisions of this part shall apply in the case of containers of less than one-half pint capacity only to the extent of requiring that such containers, whether they are filled in the United States or are imported filled, shall be liquor bottles (as defined in § 175.17), shall bear labels showing the marks and brands prescribed in Subpart D of this part, and shall be subject to the provisions of Subpart I of this part relating to reuse or refilling of liquor bottles and possession of refilled liquor bottles."

PAR. 3. Paragraph 4 is changed by deleting, in the proviso in § 175.34, the words "liquor bottles of less than one-half pint and."

PAR. 4. Paragraph 5 is changed to provide direct reference in § 175.55 to exceptions provided in Subpart H of 27 CFR Part 5.

PAR. 5. Paragraph 12 is changed to provide direct reference in § 175.85 to exceptions provided in Subpart H of 27 CFR Part 5.

PAR. 6. Paragraph 14 is changed by deleting, in the proviso in § 175.87, the words "liquor bottles of less than one-half pint and."

PAR. 7. Paragraph 16 is changed by deleting in § 175.93 the reference to "§ 175.98a" and inserting in lieu thereof "§ 175.98".

PAR. 8. Paragraph 17 is changed by deleting in § 175.94 the reference to "§ 175.98a" and inserting in lieu thereof "§ 175.98".

PAR. 9. Paragraph 19, which proposed insertion of a new section, is changed.

PAR. 10. Immediately following Paragraph 19 insert a paragraph B.

PAR. 11. In order to conform 26 CFR Part 201 to the amendment of 26 CFR Part 175, § 201.457 is amended.

This Treasury decision shall become effective on the first day of the first month which begins not less than 30 days after the date of its publication in the FEDERAL REGISTER.

[SEAL] BERTRAND M. HARDING,
Acting Commissioner of Internal Revenue.

Approved: October 12, 1964.

STANLEY S. SURREY,
Assistant Secretary of the Treasury.

PARAGRAPH A. The regulations in 26 CFR Part 175, Traffic in Containers of Distilled Spirits, are amended as follows:

PARAGRAPH 1. Section 175.1 is amended to make the provisions of that part applicable to containers of less than one-half pint, and to provide for the use of liquor bottles for purposes other than packaging distilled spirits. As amended, § 175.1 reads as follows:

§ 175.1 Containers of distilled spirits.

The regulations in this part relate to the traffic in containers of distilled spirits of a capacity of not more than five wine gallons. This part covers the manufacture, sale, and use of liquor bottles for packaging distilled spirits for other than industrial use; use of liquor bottles for purposes other than packaging distilled spirits; reports and inventories of liquor bottles; imports and exports of liquor bottles; permits; and the purchase, sale, and possession of used liquor bottles. The provisions of this part shall apply in the case of containers of less than one-half pint capacity only to the extent of requiring that such containers, whether they are filled in the United States or are imported filled, shall be liquor bottles (as defined in § 175.17), shall bear labels showing the marks and brands prescribed in Subpart D of this part, and shall be subject to the provisions of Subpart I of this part relating to reuse or refilling of liquor bottles and possession of refilled liquor bottles.

PAR. 2. Section 175.11 is amended to include vessels of less than one-half pint in the definition of container. As amended, § 175.11 reads as follows:

§ 175.11 Container.

"Container" shall mean a vessel of a capacity of not more than 5 wine gallons designed or intended for use for the sale of distilled spirits for other than industrial use.

PAR. 3. Section 175.33 is amended to permit the shipment of liquor bottles to manufacturers of bottling equipment for use in testing such equipment, and to distributors for display purposes. As amended, § 175.33 reads as follows:

§ 175.33 Persons authorized to receive liquor bottles.

No person may ship, consign, or deliver liquor bottles except to authorized bottlers to whom the assistant regional commissioner, or the Director, Alcohol and Tobacco Tax Division, in the case of States, has assigned an appropriate symbol and number for marking liquor bottles: *Provided,* That liquor bottles may be shipped pursuant to Form 98 by the manufacturer to another person for additional processing, such as coloring or cutting, where legal title and custody to such liquor bottles are retained by the manufacturer until they are delivered to the permittee-user: *Provided further,* That liquor bottles may be shipped to other persons for other uses, in accordance with §§ 175.65 and 175.66.

PAR. 4. Section 175.34 is amended to delete the requirement that the words "Federal Law Forbids Sale or Reuse of This Bottle" be marked on liquor bottles, to remove the reference to § 175.56 which is being deleted, and to exempt liquor bottles of less than one-half pint from the markings required by this section. As amended, § 175.34 reads as follows:

§ 175.34 Indicia for domestic liquor bottles.

There shall be legibly blown, etched, sand-blasted, marked by underglaze coloring, or otherwise permanently marked by any method approved by the Director, Alcohol and Tobacco Tax Division, in either the bottom or the body of each liquor bottle (a) the permit number of the manufacturer, (b) the year of the manufacture (which shall be indicated by the last two numerals), and (c) a symbol and number assigned by the assistant regional commissioner, or by the Director, Alcohol and Tobacco Tax Division, in the case of States, to represent the name of the bottler procuring the same: *Provided,* That liquor bottles which are authorized by the Director, Alcohol and Tobacco Tax Division, under §§ 175.57 and 175.58 may be manufactured and shipped, consigned, or delivered, as excepted from the marking required by this section.

PAR. 5. Section 175.55 is amended to remove any possible implication that specific bottle sizes are prescribed for liqueurs, cocktails, and certain other specialties. As amended, § 175.55 reads as follows:

§ 175.55 General.

Distilled spirits packaged for sale in domestically manufactured containers (as defined by § 175.11) shall be packaged only in liquor bottles which conform to the requirements of this part, and which conform to the standards of fill provided in Subpart H of 27 CFR Part 5 (with due regard for the exceptions provided in § 5.74 of that subpart).

§ 175.56 [Revoked]

PAR. 6. Section 175.56 is revoked.

PAR. 7. Section 175.59 is amended to reduce the number of photographs required with an application for the approval of a distinctive liquor bottle, from 25 to 12. As amended, § 175.59 reads as follows:

§ 175.59 Approval of distinctive liquor bottles.

Application in letter form for the approval of any distinctive liquor bottle, accompanied by a specimen bottle (or an authentic model or other representation acceptable to the Director, Alcohol and Tobacco Tax Division), and 12 photographs thereof, size 5" x 7", shall be submitted to the Director, Alcohol and Tobacco Tax Division. In the case of liquor bottles which the applicant in-

tends to qualify under the provisions of § 175.57, the application shall include a statement of the cost of each such bottle to the bottler. Approval of the distinctive bottle by the Director, Alcohol and Tobacco Tax Division, will be obtained, prior to submission of an application (Form 98) to the assistant regional commissioner. Such application (Form 98) shall specify the number of the bottle assigned by the Director, Alcohol and Tobacco Tax Division.

PAR. 8. Section 175.62 is amended to recognize that liquor bottles may be used for display or for testing purposes. As amended, § 175.62 reads as follows:

§ 175.62 Use and resale of liquor bottles.

No bottler shall use any liquor bottle except for packaging distilled spirits, or resell any liquor bottle except in connection with the sale of its contents, or divert any liquor bottle from his own use except upon application (Form 98) to and authorization by the assistant regional commissioner, as provided by § 175.111. (For provisions relating to furnishing of bottles for display or testing purposes, see § 175.65 or § 175.66.)

PAR. 9. A new section, § 175.65, is added to permit the use of liquor bottles for display purposes. The new § 175.65 reads as follows:

§ 175.65 Bottles to be used for display purposes.

Bottlers may furnish liquor bottles to liquor dealers for display purposes, provided that each bottle is marked to show that it is to be used for such purpose. Any paper strip used to seal the bottle shall be of solid color and without design or printing, except that the use of a border or a design, formed entirely of the legend "not genuine—for display purposes only" is permissible. The bottler shall keep records of the disposition of such bottles, showing names and addresses of consignees, dates of shipment, and size, quantity, and description of bottles.

PAR. 10. A new section, § 175.66, is added to permit the use of liquor bottles by manufacturers of bottling machinery in testing bottling machinery. The new § 175.66 reads as follows:

§ 175.66 Bottles to be used for testing bottling machinery.

Pursuant to letterhead application, the assistant regional commissioner may, with the approval of the Director, Alcohol and Tobacco Tax Division, authorize any manufacturer of bottling machinery in his region to procure a specific number of bottles from a bottler or a bottle manufacturer for use in testing bottling machinery.

PAR. 11. Section 175.75 is amended to provide for inspection of records and stocks of liquor bottles in the hands of persons other than manufacturers and bottlers. As amended, § 175.75 reads as follows:

§ 175.75 Inspection of stocks and records of liquor bottles.

The records required to be kept under the provisions of this subpart, and all stocks of liquor bottles in the hands of manufacturers, bottlers, and other persons who receive bottles pursuant to this part, shall at all times be available for inspection by the assistant regional commissioner and other duly authorized officers of the Internal Revenue Service.

PAR. 12. Section 175.85 is amended to remove any possible implication that specific bottle sizes are prescribed for liqueurs, cocktails, and certain other specialties. As amended, § 175.85 reads as follows:

§ 175.85 General.

Distilled spirits packaged for sale in imported containers (as defined by § 175.11) shall be packaged only in liquor bottles which conform to the requirements of this part, and which conform to the standards of fill provided in Subpart H of 27 CFR Part 5 (with due regard for the exceptions provided in § 5.74 of that subpart).

PAR. 13. Section 175.86 is amended to remove the reference to § 175.88 which is being deleted. A printing error is corrected by changing the third word from the end of the section from "part" to "port." As amended, § 175.86 reads as follows:

§ 175.86 Permit required.

Empty liquor bottles may be imported into the United States only pursuant to a permit issued in accordance with the provisions of §§ 175.87, 175.89, and 175.90: *Provided,* That where a permit has been issued covering the importation of liquor bottles through one port of entry, an additional permit for importation of such liquor bottles through another port will not be required if the importer furnishes photographic copies of the original permit to the collector of customs of each such other port and to the assistant regional commissioner (if the permit was not originally issued by him) of the region in which such other port is located.

PAR. 14. Section 175.87 is amended to delete the requirement that the words "Federal Law Forbids Sale or Reuse of This Bottle" be marked on liquor bottles, to remove the reference to § 175.88 which is being deleted, and to exempt liquor bottles of less than one-half pint from the markings required by this section. As amended, § 175.87 reads as follows:

§ 175.87 Indicia for empty liquor bottles.

Upon application (Form 98) by any importer or bottler, the assistant regional commissioner of the region in which the applicant is situated may, by the issuance of an appropriate permit, authorize the importation, for the packaging of either domestic or imported distilled spirits, of empty liquor bottles. The assistant regional commissioner issuing the permit will furnish a copy to the assistant regional commissioner of the region in which the port of entry is situated. There shall be legibly blown, etched, sand-blasted, marked by underglaze coloring, or otherwise permanently marked by any method approved by the Director, Alcohol and Tobacco Tax Division, either in the bottom or in the body of each such bottle imported under this provision, the name, and the name of the city or country of address, of the manufacturer, and the permit symbol and number of the bottler: *Provided,* That liquor bottles of less than one-half pint and liquor bottles which are authorized by the Director, Alcohol and Tobacco Tax Division, under §§ 175.89 and 175.90 may be imported, as excepted from the markings required by this section.

§ 175.88 [Revoked]

PAR. 15. Section 175.88 is revoked.

PAR. 16. Section 175.93 is amended to remove the reference to § 175.95 which is being deleted and to add a reference to new § 175.98a. As amended, § 175.93 reads as follows:

§ 175.93 Permit required.

Liquor bottles containing distilled spirits, other than bottles conforming to the provisions of § 175.94, may be imported into the United States only pursuant to a permit issued in accordance with the provisions of §§ 175.96 to 175.98 and § 175.100: *Provided,* That, where a permit has been issued covering the importation of filled liquor bottles through one port of entry, an additional permit for importation of such liquor bottles through another port will not be required if the importer furnishes photographic copies of the original permit to the collector of customs at each such other port and to the assistant regional commissioner (if the permit was not originally issued by him) of the region in which such other port is located.

PAR. 17. Section 175.94 is amended to delete the requirement that the words "Federal Law Forbids Sale or Reuse of This Bottle" be marked on liquor bottles, to remove the reference to § 175.95 which is being deleted, and to add a reference to new § 175.98a. As amended, § 175.94 reads as follows:

§ 175.94 Indicia.

There shall be legibly blown, etched, sand-blasted, marked by underglaze coloring, or otherwise permanently marked by any method approved by the Director, Alcohol and Tobacco Tax Division, either in the bottom or in the body of all liquor bottles containing distilled spirits imported from foreign countries the name, and the name of the city or country of address, of the manufacturer of the spirits, or of the exporter abroad, or the name, and the name of the city of address, of the importer in the United States, except as provided in §§ 175.96 to 175.98 and § 175.100.

§ 175.95 [Revoked]

PAR. 18. Section 175.95 is revoked.

PAR. 19. Section 175.101 is amended to provide for the exportation of empty liquor bottles for uses other than bottling spirits for importation into the United States. As amended, § 175.101 reads as follows:

§ 175.101 Exports.

Containers in which distilled spirits are to be exported shall not be subject to

the indicia requirements of this part and the procurement and use of containers other than liquor bottles for this purpose may be authorized under permit upon application (Form 98) to the assistant regional commissioner of the region in which the bottler is located. The manufacturer and exportation of empty liquor bottles for bottling distilled spirits abroad for importation into the United States may be authorized under permit upon application (Form 98) to the assistant regional commissioner of the region in which the bottles are to be manufactured; similarly the exportation of used liquor bottles for reuse by the original bottler abroad for packaging distilled spirits for importation into the United States may be authorized under permit issued by the assistant regional commissioner of the region in which such used bottles are stored, pursuant to an application (Form 98) filed by the importer. The exportation of empty liquor bottles for use abroad may be authorized under permit upon application (Form 98) to the assistant regional commissioner of the region from which the bottles will be exported.

PAR. B. The regulations in 26 CFR Part 201, Distilled Spirits Plants, are amended as follows:

PAR. 1. In order to conform 26 CFR Part 201 to the amendment of 26 CFR Part 175, § 201.457 is amended to read as follows:

§ 201.457 Liquor bottles.

Liquor bottles may not be used for wines containing 24 percent alcohol by volume or less or for products manufactured with such wines unless such products contain spirits other than wine spirits used in wine production. Liquor bottles may be used, but need not be used, in bottling spirits for export. (See Part 175 of this chapter for provisions respecting liquor bottles.)

(72 Stat. 1374; 26 U.S.C. 5301)

(Sec. 7805 of the Internal Revenue Code; 68A Stat. 917; 26 U.S.C. 7805)

[F.R. Doc. 64-10624; Filed, Oct. 16, 1964; 8:47 a.m.]

[T.D. 6763]

PART 250—LIQUORS AND ARTICLES FROM PUERTO RICO AND THE VIRGIN ISLANDS

PART 251—IMPORTATION OF DISTILLED SPIRITS, WINES, AND BEER

Containers of Less Than One-Half Pint

On May 5, 1964, a notice of proposed rule making to amend 26 CFR Parts 250 and 251 was published in the FEDERAL REGISTER (29 F.R. 5907). In accordance with the notice, interested parties were afforded an opportunity to submit written comments or suggestions pertaining thereto. No comments or suggestions were received within the 30-day period prescribed in the notice, and the amendments as published in the FEDERAL REGISTER are hereby adopted.

This Treasury decision shall become effective on the first day of the first month which begins not less than 30 days after date of its publication in the FEDERAL REGISTER.

[SEAL] BERTRAND M. HARDING,
Acting Commissioner of Internal Revenue.

PHILIP NICHOLS, Jr.,
Commissioner of Customs.

Approved: October 13, 1964.

STANLEY S. SURREY,
Assistant Secretary of the Treasury.

In order to extend the provisions of 26 CFR Parts 250 and 251, as they relate to size of containers, to containers of less than one-half pint, the regulations in 26 CFR Parts 250 and 251 are amended as follows:

PARAGRAPH A. 26 CFR Part 250 is amended as follows:

1. Section 250.38 is amended by striking therefrom the phrase "not less than one-half pint and". As amended, § 250.38 reads as follows:

§ 250.38 Containers of distilled spirits.

Containers of distilled spirits brought into the United States from Puerto Rico, having a capacity of not more than 1 gallon, shall conform to the requirements of Part 175 of this chapter.

(72 Stat. 1374; 26 U.S.C. 5301)

2. Section 250.203 is amended by striking therefrom the phrase "not less than one-half pint and". As amended § 250.203 reads as follows:

§ 250.203 Containers of 1 gallon or less.

Containers of distilled spirits brought into the United States from the Virgin Islands, having a capacity of not more than 1 gallon, shall conform to the requirements of Part 175 of this chapter.

(72 Stat. 1374; 26 U.S.C. 5301)

PARAGRAPH B. 26 CFR Part 251 is amended as follows:

1. Section 251.56 is amended so that it will apply to containers of less than one-half pint and to make clarifying changes. As amended, § 251.56 reads as follows:

§ 251.56 Distilled spirits containers of a capacity of not more than 1 gallon.

Bottled distilled spirits imported into the United States for sale shall be bottled in liquor bottles which conform to the requirements of Part 175 of this chapter and 27 CFR Part 5, and shall be stamped in accordance with this part. Empty containers imported for the packaging of distilled spirits shall conform to the requirements of Part 175 of this chapter. (For Customs requirements as to marking, see 19 CFR Parts 11 and 12.)

(Sec. 7805 of the Internal Revenue Code; 68A Stat. 917; 26 U.S.C. 7805)

[F.R. Doc. 64-10625; Filed, Oct. 16, 1964; 8:47 a.m.]

Title 36—PARKS, FORESTS, AND MEMORIALS

Chapter III—Corps of Engineers, Department of the Army

PART 311—PUBLIC USE OF CERTAIN RESERVOIR AREAS

Additional Areas

The Secretary of the Army having determined that the use of the following reservoir areas by the general public for boating, swimming, bathing, fishing, and other recreational purposes will not be contrary to the public interest and will not be inconsistent with the operation and maintenance of the reservoirs for their primary purposes, hereby prescribes rules and regulations for their public use, pursuant to the provisions of section 4 of the Flood Control Act of 1944, as amended (76 Stat. 1195), adding the reservoirs to the list in § 311.1, as follows:

§ 311.1 Areas covered.

* * * * *

ILLINOIS

Carlyle Reservoir Area, Kaskaskia River.

* * * * *

KENTUCKY

* * * * *

Fishtrap Reservoir Area, Levisa Fork.
Grayson Reservoir Area, Little Sandy River.

* * * * *

OHIO

* * * * *

Delaware Reservoir Area, Olentangy River.

* * * * *

VIRGINIA

* * * * *

John W. Flannagan Reservoir Area, Pound River.
North Fork of Pound Reservoir Area, North Fork of Pound River.

* * * * *

WEST VIRGINIA

* * * * *

Summersville Reservoir Area, Gauley River.

[Regs., Sept. 24, 1964, ENGCW-OM] (Sec. 4, 58 Stat. 889, as amended; 16 U.S.C. 460d)

L. H. WALKER, Jr.,
Brigadier General, U.S. Army, Acting The Adjutant General.

[F.R. Doc. 64-10614; Filed, Oct. 16, 1964; 8:47 a.m.]

Title 30—MINERAL RESOURCES

Chapter I—Bureau of Mines, Department of the Interior

PART 45—TITLE II, FEDERAL COAL MINE SAFETY ACT OF 1952

Interpretations

On page 1551 of the March 9, 1957, issue of the FEDERAL REGISTER, an interpretation of section 209(g)(1) of the Federal Coal Mine Saftey Act was published. Section 45.46-1 (f) and (j) are hereby amended as follows:

§ 45.46–1 Minimum requirements.

* * * * *

(f) (1) Unless water lines, equipped with outlet valves at intervals of not more than 500 feet and capable of delivering 50 gallons of water per minute at a nozzle pressure of 50 pounds per square inch, are installed along main and secondary haulage roads and extend to the working sections; and unless 1,000 feet of fire hose with fittings suitable for connection with such water lines are available; two portable water-tank cars of at least 1,000 gallons capacity each, equipped with a high-pressure pump and not less than 300 feet of fire hose with nozzles, or two portable chemical cars containing or carrying equivalent protection, shall be provided: *Provided, however,* That one of the two water-tank cars or chemical cars may be replaced by (i) a portable high pressure rock-dusting machine fitted with at least 250 feet of hose, with at least 60 sacks of rock dust in good condition near it at all times, or (ii) a portable foam-generating machine with facilities for supplying the machine with 30 gallons of water per minute at a pressure of 30 pounds per square inch for a period of not less than 20 minutes.

(2) These units shall be stationed at strategic locations and ready for use at all times. Where two or more adjacent mines are connected by track, one of the two water-tank cars or chemical cars (or their substitutes) required for each mine may be a common unit.

* * * * *

(j) At every mine there shall be available for emergency use the following materials: 1,000 board feet of brattice boards, 3 rolls of brattice cloth, 2 hand saws, 25 pounds 8^d nails, 25 pounds 10^d nails, 25 pounds 16^d nails, 3 claw hammers, 25 bags of wood fiber plaster or 10 bags of cement (or equivalent material for stoppings), and in addition 5 tons of rock dust.

* * * * *

MARLING J. ANKENY,
Director, Bureau of Mines.

OCTOBER 13, 1964.

[F.R. Doc. 64–10613; Filed, Oct. 16, 1964; 8:46 a.m.]

Title 41—PUBLIC CONTRACTS AND PROPERTY MANAGEMENT

Chapter 8—Veterans Administration

PART 8–3—PROCUREMENT BY NEGOTIATION

PART 8–4—SPECIAL TYPES AND METHODS OF PROCUREMENT

PART 8–16—PROCUREMENT FORMS

PART 8–75—DELEGATIONS OF AUTHORITY

Miscellaneous Amendments

1. Section 8–3.604–6 is revised to read as follows:

§ 8–3.604–6 Procurement and payment.

(a) Each purchase costing $15.00 or more will be supported by a cash register receipt, invoice, sales slip, or other sales document which shall, if possible, contain an itemized listing of the items purchased and be signed by the vendor or his agent. When it is not possible to secure the listing or signature a subvoucher containing this information will be prepared, signed by the purchaser, and attached to the receipt.

(b) Each purchase costing less than $15.00 shall be supported as required in paragraph (a) of this section, except that the signature of the vendor or agent need not be secured. If a receipt cannot be secured the purchaser shall prepare and sign Standard Form 1165, Receipt for Cash—Subvoucher, listing thereon the name of the vendor and the articles or services purchased.

2. Section 8–3.606–5 is revised to read as follows:

§ 8–3.606–5 Agency implementation.

(a) Blanket purchase arrangements for open-market transactions may be made without regard to a limitation of time or dollar amount. The existence of blanket purchase arrangements does not in any way eliminate the requirement for obtaining reasonable competition. No single purchase under blanket purchase arrangements for open-market transactions will exceed $2,500.

(b) The duplicate and triplicate copies of the VA Form 07–2237, Request, Turn-in and Receipt for Property or Services, requesting the purchase will be used as the receiving report and property voucher for each individual purchase made under these arrangements.

(c) Agreements will be reviewed periodically to insure that they are advantageous to the Veterans Administration. Cancellation shall be effected when an adverse determination is made.

(d) Items procured under blanket purchase arrangements will be analyzed periodically to determine if they can be procured more economically by consolidating requirements and making periodic buys.

(e) Blanket purchase arrangements made under existing contracts are restricted only to the period of the contract.

3. Section 8–4.5101 is revised to read as follows:

§ 8–4.5101 Delegation of authority to purchase narcotics.

Heads of field stations are authorized to certify to the appropriate District Director, Internal Revenue Service, on the form prescribed by the Treasury Department, the names of the Chief and Assistant Chief, Supply Division or Chief, Business Services Division and one Contracting Officer as accredited officials of the Veterans Administration to purchase narcotics, in accordance with Articles 93 and 94, Bureau of Narcotics Regulation No. 5. The Assistant Director, Supply Service, VA Supply Depot, Somerville, N.J., will certify to the District Director, Internal Revenue Service that the Chief, Marketing Division for Drugs and Chemicals, and the Supervisory Procurement Agent are accredited officials of the Veterans Administration to purchase narcotics. Credentials will be renewed each fiscal year.

4. Sections 8–16.350 and 8–16.350–1 are revised to read as follows:

§ 8–16.350 Use of purchase orders.

Except for drop shipment contracts and as provided in FPR 1–3.6 and subpart 8–3.6 or in this subpart 8–16.3, all purchases of supplies, equipment, and services will be by means of one of the purchase forms prescribed in these subparts.

§ 8–16.350–1 Special forms.

Where departmental forms are provided for specific types of purchase, such forms will be used in lieu of those provided in FPR 1–3.6 and subpart 8–16.3.

5. In § 8–75.101(a), a new subparagraph (8) is added and the former subparagraphs (8) and (9) are redesignated (9) and (10) so that the new and redesignated material reads as follows:

§ 8–75.101 Delegation.

(a) * * *

(8) Chief, Business Services Division, VA field stations.

(9) Chief, Central Office Building and Supply Division.

(10) Chief, Marketing Division.

* * * * *

6. In § 8–75.201–3, the section heading is amended to read as follows:

§ 8–75.201–3 Architectural and Engineering Services; central office.

7. Section 8–75.201–5 is revised to read as follows:

§ 8–75.201–5 Construction contracts; field stations, supply depots.

The Chief, Supply or Business Services Division, at a field station, the Assistant Director, Supply Service for a VA Supply Depot, and any employee designated by them in accordance with § 8–75.101(b) are authorized to execute, award, and administer contracts for construction projects assigned by Central Office Construction Service or those accomplished with station or depot funds. Contracting Officers, in executing, awarding, and administering construction contracts, including those for maintenance and repair projects will be guided by Federal Procurement Regulations, Veterans Administration Procurement Regulations, and procedures established by the Assistant Administrator for Construction.

8. Section 8–75.201–8 is revised to read as follows:

§ 8–75.201–8 Issue of Government bills of lading—Transportation of Property.

The Chief, Transportation Section at a VA Supply Depot is delegated authority to issue and sign as issuing officer, Government bills of lading for the transportation of supplies, materials, and equipment. He, in turn, may designate one or more freight rate specialists under his supervision, and authority is hereby delegated to such subordinates, to issue and sign as issuing officer, Government bills of lading for the transportation of supplies, materials, and equipment. Designations will be in writing and specifically

set forth the scope and limitation of the designee's authority.

9. Section 8–75.201–10 is revised to read as follows:

§ 8–75.201–10 Architectural and engineering services; field stations, supply depots.

The Chief, Supply or Business Services Division at a field station, the Assistant Director, Supply Service for a VA Supply Depot, and any employee designated by them in accordance with § 8-75.101(b) are authorized to execute, award, and administer contracts for the acquisition of architectural and engineering services when the cost of such services are chargeable to station or depot funds.

(Sec. 205(c), 63 Stat. 390, as amended, 40 U.S.C. 486(c); sec. 210(c), 72 Stat. 1114, 38 U.S.C. 210(c))

These regulations are effective immediately.

Approved: October 12, 1964.

By direction of the Administrator.

[SEAL] A. H. MONK,
Associate Deputy Administrator.

[F.R. Doc. 64–10628; Filed, Oct. 16, 1964; 8:47 a.m.]

Title 43—PUBLIC LANDS: INTERIOR

Chapter II—Bureau of Land Management, Department of the Interior

SUBCHAPTER C—MINERALS MANAGEMENT (3000)

[Circular 2168]

PART 3210—ACQUIRED LANDS LEASING ACT

Subpart 3210—Acquired Lands Leasing Act: General

On page 6650 of the FEDERAL REGISTER of May 21, 1964, there was published a proposal to amend paragraph (a) of § 3212.1.

The primary purpose of the proposed amendment was to clarify the nature of the content of applications for mineral permits and leases and also of the supplemental information to be submitted with such applications.

Interested persons were given 30 days within which to submit written comments, suggestions, or objections with respect to the proposed amendment. After consideration of all of the comments, suggestions, and objections received during that period, the following changes and modifications have been made in the proposed amendment. The requirement that offers to lease and applications be accompanied by a copy of the deed by which the United States acquired its interest in the land or minerals and by a copy of any deed by which the United States may have conveyed any interest therein has been eliminated. The requirement that unsurveyed lands be described in the deed to the United States has been amplified by a reference to any document by which the United States acquired its interest other than by deed, as in a declaration of taking or a judgment of a court of competent jurisdiction vesting title in the United States. A number of typographical errors which appeared in the original publication of the proposed amendment have also been corrected.

The amendment is hereby adopted as set forth below and shall become effective 30 days after publication in the FEDERAL REGISTER.

Paragraph (a) of § 3212.1 is amended to read as follows:

§ 3212.1 Supplemental information required in offers and applications for leases and permits; place of filing.

(a) Each offer or application for a lease or permit must (1) contain a statement that applicant's interest, direct or indirect, in leases, permits, or applications for similar minerals does not exceed the maximum chargeable acreage permitted to be held for that mineral in federally-owned acquired lands in the same State; (2) be accompanied by a map upon which the desired lands are clearly marked showing their location with respect to the administrative unit or project of which they are a part (such map need not be submitted where the desired lands have been surveyed under the rectangular system of public land surveys, and the land description can be conformed to that system), and (3) describe the lands for which the lease or permit is desired as follows:

(i) If the land has been surveyed under the rectangular system of public land surveys, and the description can be conformed to that system, the land must be described by legal subdivision, section, township, and range. Where the description cannot be conformed to the public land surveys, any boundaries which do not so conform must be described by metes and bounds, giving courses and distances between the successive angle points with appropriate ties to the nearest existing official survey corner. If not so surveyed and if within the area of the public land surveys, the land must be described by metes and bounds, giving courses and distances between the successive angle points on the boundary of the tract, and connected with a reasonably nearby corner of those surveys by courses and distances.

(ii) If the lands have not been surveyed under the rectangular system of public land surveys, and the tract is not within the area of the public land surveys, it must be described as in the deed or other document by which the United States acquired title to the lands or minerals. If the desired land constitutes less than the entire tract acquired by the United States, it must be described by courses and distances between successive angle points on its boundary tying by course and distance into the description in the deed or other document by which the United States acquired title to the land. In addition, if the description in the deed or other document by which the United States acquired title to the lands does not include the courses and distances between the successive angle points on the boundary of the desired tract, the description in the offer must be expanded to include such courses and distances.

(iii) If an acquisition tract number has been assigned by the acquiring agency to the identical tract desired, a description by such tract number will be accepted. Such offer or application must be accompanied by the map required by subparagraph (2) of this paragraph.

(iv) Where an offer or application includes any accreted lands that are not described in the deed to the United States, such accreted lands must be described by metes and bounds, giving courses and distances between the successive angle points on the boundary of the tract, and connected by courses and distances to an angle point on the perimeter of the acquired tract to which the accretions appertain.

(v) The offeror or applicant must, if practicable, give the name of the administrative unit or project of which the lands applied for are a part.

* * * * * *

JOHN A. CARVER, Jr.,
Acting Secretary of the Interior.

OCTOBER 13, 1964.

[F.R. Doc. 64–10615; Filed, Oct. 16, 1964; 8:47 a.m.]

Proposed Rule Making

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[7 CFR Part 905]

ORANGES, GRAPEFRUIT, TANGERINES, AND TANGELOS GROWN IN FLORIDA

Proposed Approval of Expenses and Fixing of Rate of Assessment for 1964–65 Fiscal Period

Consideration is being given to the following proposals submitted by the Growers Administrative Committee, established under marketing agreement, as amended, and Order No. 905, as amended (7 CFR Part 905), regulating the handling of oranges, grapefruit, tangerines, and tangelos grown in Florida, effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), as the agency to administer the terms and provisions thereof:

(a) That the Secretary of Agriculture find that expenses not to exceed $143,000 will be necessarily incurred during the fiscal period August 1, 1964, to July 31, 1965, for the maintenance and functioning of the committee established under the aforesaid amended marketing agreement and order.

(b) That the Secretary of Agriculture fix, as the share of such expenses which each handler who first handles fruit shall pay during the aforesaid fiscal period in accordance with the aforesaid amended marketing agreement and order, the rate of assessment at six mills ($0.006) per standard packed box of fruit handled by such handler as the first handler thereof during such fiscal period.

(c) Terms used in the amended marketing agreement and order shall, when used herein, have the same meaning as is given to the respective term in said amended marketing agreement and order.

All persons who desire to submit written data, views, or arguments in connection with the aforesaid proposals should file the same, in quadruplicate, with the Hearing Clerk, United States Department of Agriculture, Room 112, Administration Building, Washington, D.C., 20250, not later than the 10th day after the publication of this notice in the FEDERAL REGISTER. All written submissions made pursuant to this notice will be made available for public inspection at the office of the Hearing Clerk during regular business hours (7 CFR 1.27(b)).

Dated: October 14, 1964.

PAUL A. NICHOLSON,
Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[F.R. Doc. 64–10642; Filed, Oct. 16, 1964; 8:49 a.m.]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Parts 45, 121]

OLEOMARGARINE IDENTITY STANDARD; FOOD ADDITIVES DELTA-DECALACTONE AND DELTA-DODECALACTONE

Proposals To Amend Identity Standard and To Issue Regulation Establishing Safety of Food Additive

1. Pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 401, 701, 52 Stat. 1046, 1055, as amended 70 Stat. 919, 72 Stat. 948; 21 U.S.C. 341, 371) and in accordance with the authority delegated to the Commissioner of Food and Drugs by the Secretary of Health, Education, and Welfare (21 CFR 2.90; 29 F.R. 471), notice is given that a petition has been filed by Lever Brothers Company, 390 Park Avenue, New York, N.Y., proposing that the identity standard for olemargarine (21 CFR 45.1) be amended to permit the use of delta-decalactone and delta-dodecalactone as optional artificial flavoring ingredients.

It is proposed that § 45.1 be amended by redesignating the text of paragraph (a) (3) (iv) as (a) (3) (iv) (*a*), and by adding thereto a new item, designated as (a) (3) (iv) (*b*). As amended, the affected portions will read:

§ 45.1 **Oleomargarine, margarine; identity; label statement of optional ingredients.**

* * * * *

(a) * * *

(3) * * *

(iv) (*a*) The artificial flavoring diacetyl added as such or as starter distillate or produced during the preparation of the product as a result of the addition of citric acid or harmless citrates.

(*b*) The artificial flavorings delta-decalactone, in an amount not to exceed 10 parts per million, or delta-dodecalactone, in an amount not to exceed 20 parts per million by weight of the finished oleomargarine, or a combination of these, used in accordance with § 121.1144 of this chapter.

2. The Commissioner of Food and Drugs, having considered the relevant information in this matter, proposes on his own initiative to amend the food additive regulations to provide for the safe use of the aforementioned flavorings in the subject food. Therefore, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409(d), 72 Stat. 1787; 21 U.S.C. 348(d)), and under the authority delegated to him by the Secretary of Health, Education, and Welfare (21 CFR 2.90; 29 F.R. 471), the Commissioner proposes that § 121.1144 be amended to read as follows:

§ 121.1144 Lactones.

The following food additives may be used in margarine, alone or in combination, as artificial flavoring agents:

(a) Delta-decalactone, in an amount not exceeding 10 parts per million by weight of the finished margarine.

(b) Delta-dodecalactone, in an amount not exceeding 20 parts per million by weight of the finished margarine.

All interested persons are invited to submit written comments or objections regarding the proposals in this notice within 30 days following the date of its publication in the FEDERAL REGISTER. Such comments or objections should be submitted, preferably in quintuplicate, addressed to the Hearing Clerk, Department of Health, Education, and Welfare, Room 5440, 330 Independence Avenue SW., Washington, D.C., 20201. Comments or objections may be accompanied by a memorandum or brief in support thereof.

Dated: October 13, 1964.

GEO. P. LARRICK,
Commissioner of Food and Drugs.

[F.R. Doc. 64–10629; Filed, Oct. 16, 1964; 8:47 a.m.]

FEDERAL AVIATION AGENCY

[14 CFR Parts 40, 42]

[Docket No. 6258; Notice 64–48]

MAINTENANCE LOG

Notice of Proposed Rule Making

The Federal Aviation Agency is considering amending § 40.507 of Part 40 of the Civil Air Regulations and § 42.507 of Part 42 of the Civil Air Regulations. The purpose of these amendments is to delete the last sentence of each of those sections relating to the posting in the airplane maintenance log of time since last overhaul of the airframe and engines.

As presently written these sections require that the maintenance log shall contain information from which the flight crew may readily determine the time since last overhaul of the airframe and engines.

Interested persons are invited to participate in the making of the proposed rules by submitting such written data, views, or arguments as they desire. Communications should identify the notice or docket number and be submitted in duplicate to the Federal Aviation Agency, Office of the General Counsel: Attention, Rules Docket, 800 Independence Avenue SW., Washington, D.C., 20553. All communications received on or before 30 days after the date of this

notice will be considered by the Administrator before taking action on the proposed rule. The proposal contained in this notice may be changed in the light of comments received. All comments submitted will be available, both before and after the closing date for comments, in the Docket Section for examination by interested persons.

Notice No. 63–20 (28 F.R. 6083) in proposing several miscellaneous amendments to Part 40 of the Civil Air Regulations proposed to delete this language from that part. However, the proposal was not adopted as a part of the final rule in the light of certain comments, made by representatives of certain pilots' and flight engineers' organizations, that the information was of importance to flight crews.

Since the date of those comments, the Air Transport Association has requested that this provision, among others, be reconsidered by the Agency. It is the Association's position that the information on overhaul times is rarely used and that the requirement serves no useful purpose. The Association further stated that, if flight crews should feel at some time that the information is in fact necessary, it is readily available in other records. Under the approved continuous maintenance programs now in use, the requirement is almost impossible to comply with since there is, in effect, no such thing as time since last overhaul of the airframe. When sectionalized overhaul of turbine engines becomes more prevalent this would present further problems.

In the light of the above, the Agency has reconsidered the matter and is of the opinion that, since overhaul time limits are generally based on reliability that can reasonably be expected throughout the period between overhauls (because of progressive maintenance and overhaul systems now in use), the requirement is no longer necessary. This should be especially so under the new Air Carrier Continuous Airworthiness Program which was adopted on May 13, 1964, and which becomes effective on October 19, 1964.

This proposal is subject to the Federal Aviation Agency recodification program announced in Draft Release 61–25 (26 F.R. 10698). The final rule, if adopted, may be in recodified form; however, the recodification itself will not alter the substantive contents proposed herein.

In consideration of the foregoing, it is proposed to amend Part 40 of the Civil Air Regulations by striking out the last sentence of § 40.507 and to amend Part 42 of the Civil Air Regulations by striking out the last sentence of § 42.507.

These amendments are proposed under the authority of sections 313(a) and 601–610 of the Federal Aviation Act of 1958 (49 U.S.C. 1354(a) and 1421–1430).

Issued in Washington, D.C., on October 15, 1964.

C. W. WALKER,
Acting Director,
Flight Standards Service.

[F.R. Doc. 64–10677; Filed, Oct. 16, 1964; 8:50 a.m.]

[14 CFR Part 91 [New]]

[Docket No. 6247; Notice 64–47]

FLIGHT TEST AREAS

Notice of Proposed Rule Making

The Federal Aviation Agency is considering amending Part 91 [New] of the Federal Aviation Regulations to eliminate the requirement of obtaining an approved flight test area for the flight testing of aircraft.

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the regulatory docket or notice number and be submitted in duplicate to the Federal Aviation Agency, Office of the General Counsel: Attention Rules Docket, 800 Independence Avenue SW., Washington, D.C., 20553. All communications received on or before November 23, 1964, will be considered by the Administrator before taking action on the proposed rule. The proposal contained in this notice may be changed in the light of comments received. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons.

Section 91.93 requires that no person may flight test an aircraft except over open water or sparsely populated areas having light air traffic and within a flight test area approved by the Administrator. It defines "flight test" and "basic airworthiness," and prescribes detailed procedures to be followed in submitting applications for approval or renewal of flight test areas. Section 91.167 requires that an appropriately rated pilot must test fly an aircraft that has been repaired or altered in a manner that may have appreciably changed its flight characteristics or substantially changed its operation in flight, before carrying persons other than crewmembers in such aircraft, unless ground tests or inspections show that the flight characteristics of the aircraft have not been appreciably altered.

The proposed amendment to § 91.93 omits reference to approved flight test areas, but retains the requirement that pilots while flight testing aircraft must avoid congested areas and areas of high density air traffic. The amendment to § 91.167 deletes the word "test" with respect to flights to distinguish an operational flight check of repaired or altered aircraft from flight tests of noncertificated or substantially modified aircraft for determining basic airworthiness.

Approved flight test areas do not positively segregate flight test activities from other traffic. Moreover, it appears that the approval of flight test areas serves little practical purpose since many of the areas are so large and overlapping that other traffic could not avoid them if the areas were depicted on aeronautical charts, which they are not. For example, the entire State of Kansas is a flight test area. Since many approved flight test areas encompass cities and towns, it is the portion of § 91.93 requiring pilots to avoid congested areas and not the confinement of aircraft to the approved area that enhances safety to persons and property.

It would appear more expedient for amateur builders, who submit approximately 90 percent of the applications for flight test areas, to conduct their flight tests without the requirement for approved areas since they could do so without loss of see and avoid capability and be in compliance with other applicable regulations.

Manufacturers of high performance aircraft generally conduct their production flight test activities in positive control airspace which provides complete separation from other aircraft, or in accordance with local procedures developed by the manufacturer and air traffic control. This proposed regulation will not alter FAA/manufacturers operational agreements and continuation of these arrangements is expected. The majority of experimental and engineering flight tests of high performance aircraft are conducted in the Edwards Air Force Base, Calif., restricted area complex.

The Federal Aviation Agency has the authority and responsibility, with respect to civil aircraft, to determine when a flight test is required and to place necessary operating restrictions on the flight in the interests of safety. Military flight tests generally are conducted in restricted areas. Therefore, when the character of the flight test or the aircraft indicates the existence of special circumstances, the operation may be confined within a specified area while, in the ordinary case, the burden of obtaining approval for an impractical flight test area would be eliminated.

It is recognized that pilots of high performance aircraft operating at high altitudes and speeds would have difficulty in most parts of the United States in avoiding a flight path where the potential impact area would include a congested area; however, it is the intent of this proposal that such operations must be conducted in a location that would eliminate this hazard to the extent possible.

In consideration of the foregoing, it is proposed to amend §§ 91.93 and 91.167 of Part 91 [New] of Chapter I of Title 14 of the Code of Federal Regulations as follows:

§ 91.93 Flight tests.

(a) No person may flight test an aircraft—

(1) Over any congested area of a city, town, or settlement, or over any open air assembly of persons; or

(2) In any area of high density air traffic.

(b) Each person flight testing high performance aircraft at high altitudes and speeds shall, to the extent possible, avoid a flight path that would include any congested area within the potential impact area of the aircraft.

§ 91.167 Carrying persons other than crewmembers after repairs or alterations.

(a) No person may carry any person (other than crewmembers) in an aircraft that has been repaired or altered

in a manner that may have appreciably changed its flight characteristics, or substantially affected its operation in flight, until an appropriately rated pilot, with at least a private pilot's certificate, flies the aircraft and logs the flight in the aircraft records.

(b) Paragraph (a) of this section does not require that the aircraft be flown if ground tests or inspections, or both, show conclusively that the repair or alteration has not appreciably changed the flight characteristics, or substantially affected the flight operation of the aircraft.

This amendment is proposed under the authority of sections 307 and 313(a) of the Federal Aviation Act of 1958 (49 U.S.C. 1348 and 1354).

Issued in Washington, D.C., on October 12, 1964.

CLIFFORD P. BURTON,
Acting Director,
Air Traffic Service.

[F.R. Doc. 64-10609; Filed, Oct. 16, 1964; 8:46 a.m.]

SMALL BUSINESS ADMINISTRATION

[13 CFR Part 107]

SMALL BUSINESS INVESTMENT COMPANIES

Notice of Proposed Rule Making

Notice is hereby given that pursuant to authority contained in section 308 of the Small Business Investment Act of 1958, Public Law 85-699, 72 Stat. 694, as amended, it is proposed to amend, as set forth below, Part 107 of Subchapter B, Chapter I of Title 13 of the Code of Federal Regulations, as revised in 27 F.R. 9743-9754, and amended in 28 F.R. 681, 1627, 3021, 10868, 12250, and 29 F.R. 5223, 7144, 10499, 12109, by amending present §§ 107.501, 107.704(c)(5), and 107.713, and adding thereto a new § 107.650. Prior to the final adoption of such amendments, consideration will be given to any comments or suggestions pertaining thereto which are submitted in writing, in triplicate, to the Investment Division, Small Business Administration, Washington 25, D.C., within a period of 30 days of the date of this notice in the FEDERAL REGISTER.

Information. On June 2, 1964, notice of proposed rule making was published in the FEDERAL REGISTER (29 F.R. 7151) concerning amendment of §§ 107.704(c)(5) and 107.713 *Common tenancy,* to permit two or more Licensees whose paid-in capital and paid-in surplus from private sources (excluding organizational expense) do not in the aggregate exceed $750,000 to employ, with prior SBA approval, a common general manager. After due and careful consideration of the comments received, SBA has determined to republish the amendments under consideration, in revised form, as set forth below. It is proposed that the first paragraph of § 107.704(c)(5) be amended to provide that, without prior SBA approval, a Licensee shall not have an officer or a director who is at the same time an officer or director of another Licensee, nor shall 10 or more percent of the stock of any Licensee be owned or controlled, directly or indirectly, by an officer or director of, or by any party owning or controlling, directly or indirectly, 10 or more percent of the stock of another Licensee. No change is proposed in the present exception, in § 107.704(c)(5), permitting an attorney performing legal service for Licensees to serve as secretary or clerk for more than one Licensee. The revised proposal with respect to employment of a common manager, set forth in subdivision (ii) of § 107.704(c)(5), would authorize two or more Licensees having paid-in capital and paid-in surplus from private sources aggregating not more than $800,000 to employ, subject to prior SBA approval, an individual or a non-Licensee concern to serve as their common general manager. An individual serving serving as manager would be deemed an officer of each such Licensee for the purposes of the SBIC Regulation. At least 50 percent of the total amount of joint financing participated in by Licensees under common management over the period of a fiscal year would have to consist of individual loans or equity investments of $150,000 or less. The employment agreement submitted for SBA approval must include relevant particulars pertaining to the qualifications of the manager; the basis of compensation; period of employment; requirement for the referral of potential loans or investments by the manager to all Licensees of the group so that each may have an equal opportunity to participate in or otherwise furnish the necessary financing; and such other information as may assist SBA in determining whether approval would be consonant with the purposes of the Act.

As set forth below, the proposed amendments would add a new § 107.650 dealing with commitments. It would authorize Licensees to charge a reasonable commitment fee in connection with the issuance of loan commitments or commitments to furnish equity financing to small business concerns. Where a Licensee enters into a 5-year commitment to provide financing up to a stipulated maximum amount, with disbursement of the whole or any part thereof to be made on the request of the small business concern, the proposal would make it lawful (notwithstanding the maturity provisions of §§ 107.501 and 107.601) for repayment to be made as follows: (1) Funds advanced during the first two years may have a common maturity date coinciding with the termination date of the commitment; and (2) funds subsequently advanced during the commitment period may be for a period of three years from the respective dates of disbursement. Repayment of each advance made could not be required at an annual average rate in excess of the principal amount thereof divided by the number of years of the applicable repayment period. Where a Licensee issues a commitment to a small business concern, and the agreement carries with it options or warrants entitling Licensee to purchase shares of its stock, the proposal would make it lawful for the Licensee to acquire stock pursuant to such options or warrants (1) up to the full amount of any funds disbursed and (2) up to 25 percent of any undisbursed portion of the commitment as of the termination date thereof. The purchase price per share must be not less than sound book value at the time the options or warrants were issued, as provided in § 107.704(k).

It is proposed that § 107.501 shall be amended by adding a new paragraph (q) thereto with respect to "puts and calls." It would authorize a Licensee, at the time that it acquires equity securities from a small business concern, to enter into an agreement with the latter providing for a right on the part of the Licensee, subject to the following terms and conditions, to require the repurchase of such stock: (1) If the stock is acquired pursuant to equity securities evidencing an indebtedness, such indebtedness shall be unsecured and the note or debenture shall not be endorsed or guaranteed by any of the shareholders or principals of the small business concern; (2) where the stock is acquired by direct purchase from the issuer, the repurchase price may not exceed book value per share when the demand for repurchase is made or an agreed multiple of earnings per share for any appropriate period designated by the parties, whichever is higher, or if the stock is acquired by conversion of a debt instrument or through the exercise of stock warrants or options, the repurchase price may not be greater than book value per share at the time demand for repurchase is made; (3) Licensee's demand for repurchase may be made upon 3 months' advance notice in writing at any time after 5 years from the date of acquiring such stock, in the case of a direct stock purchase, or the date of issuance of the equity securities where such stock was acquired through the exercise of conversion rights, or stock options or warrants subject, however, to the prohibition that such demand may not be effectuated at a time when the issuer concern is or will thereby be rendered insolvent or unable to meet its debts as they mature; (4) the repurchase may be made only to the extent of earned surplus available for that purpose; (5) the issuer concern shall have the right to call for redemption of such stock at the same price and upon the same terms and conditions as govern the Licensee's right to demand a repurchase thereof; and (6) the agreement shall be subject to applicable terms, conditions and requirements of State or Federal law relevant to the particular transaction.

It is proposed to amend the Regulations Governing Small Business Investment Companies as follows:

1. By deleting paragraph (c)(5) of § 107.704 *Activities of Licensee,* in its entirety, and substituting a new paragraph (c)(5). As amended, § 107.704(c)(5) would read as follows:

(5) Without the prior written consent of SBA, a Licensee shall not have an officer or a director who at the same time is either an officer or director of any other Licensee, nor shall 10 or more

percent of the stock of any Licensee be owned or controlled, directly or indirectly, by an officer or director of, or by any party owning or controlling, directly or indirectly, 10 or more percent of the stock of another Licensee, with the following exceptions:

(i) *Attorneys.* An attorney performing legal services for Licensees may serve as secretary or clerk for more than one Licensee; and

(ii) *Common Managers.* Subject to prior SBA approval, two or more Licensees having paid-in capital and paid-in surplus from private sources aggregating not more than $800,000 (exclusive or organizational expenses) may employ an individual or a non-Licensee concern to serve as their common general manager. An individual serving as manager shall be deemed an officer of each Licensee for the purposes of these regulations. Notwithstanding the provisions of § 107.708 (b), at least 50 percent of the total amount of joint financing participated in by Licensees under common management during any fiscal year shall consist of loans or equity investments of $150,000 or less.

The proposed employment agreement submitted for SBA approval shall set forth relevant particulars pertaining to the identity and qualifications of the manager, the basis of compensation, effective period of employment, and such other factors bearing on the transaction as may assist SBA in determining whether approval would be consonant with the purposes of the Act. The agreement shall include adequate provision requiring the manager to refer each potential loan or investment to all Licensees of the group and afford them equal opportunity to participate in or otherwise provide the necessary financing.

2. By adding a new paragraph (q) to § 107.501 *Equity capital for incorporated small business concerns,* which would read as follows:

§ 107.501 Equity capital for incorporated small business concerns.

* * * * *

(q) *Puts and calls.* At the time that a Licensee acquires shares of stock of a small business concern as a direct stock purchase or pursuant to Equity Securities providing for conversion rights or stock options or warrants, it may enter into an agreement with the issuer providing for a right on the part of the Licensee to require the issuer to repurchase any of such shares of its stock acquired by the Licensee. The agreement shall be subject to the following terms:

(1) If the shares of stock are acquired pursuant to Equity Securities evidencing an indebtedness, such indebtedness shall be unsecured and the note or debenture shall not be guaranteed or endorsed by any of the shareholders or principals of the small business concern.

(2) Where the stock is acquired by conversion of a debt instrument or by the exercise of stock warrants or options, the repurchase price shall be no greater than the book value per share at the time that the demand for repurchase is made. Where the stock is acquired by direct purchase from the issuer, the repurchase price shall not exceed the higher of (i) the book value per share at the time that demand for repurchase is made or (ii) an agreed multiple of earnings per share for any appropriate period designated by the parties.

(3) Licensee may demand repurchase upon giving the small business concern at least 3 months advance notice in writing at any time after 5 years from (i) the date of acquisition of such stock, in the case of a direct stock purchase or (ii) the date of issuance of the Equity Securities where such stock was acquired through the exercise of conversion rights, or stock options or warrants: *Provided, however,* That the demand for repurchase shall not be effectuated at a time when the small business concern is or will thereby be rendered insolvent or unable to meet its debts as they mature.

(4) The repurchase may be made only to the extent of earned surplus available for that purpose.

(5) The small business concern shall have the right to call for the redemption of such stock at the same price and subject to the same terms and conditions as are applicable to Licensee's right to demand a repurchase thereof.

(6) The agreement shall be subject to applicable terms, conditions and requirements of State or Federal law, if any, that may be relevant to the particular transaction.

3. By adding a new § 107.650 *Commitments,* which would read as follows:

§ 107.650 Commitments.

(a) A Licensee is authorized to enter into a loan commitment or a commitment to furnish equity financing to a small business concern. A reasonable commitment fee may be charged.

(b) Where a Licensee enters into a 5-year commitment to finance an eligible small business concern up to a stipulated maximum amount, disbursement of the whole or any part thereof to be made on the request of such concern, it shall be lawful (notwithstanding the maturity provisions of §§ 107.501 and 107.601) to provide for repayment as follows: (1) Any funds advanced during the first two years may have a common maturity date coinciding with the termination date of the commitment; and (2) any funds subsequently advanced during the commitment period may be for a period of three years from respective dates of disbursement. Repayment of each advance made shall not be required at an annual average rate in excess of the principal amount thereof divided by the number of years of the applicable repayment period.

(c) Where a Licensee enters into a commitment, as described in paragraph (b) of this section, and the agreement carries with it options or warrants entitling Licensee to purchase shares of stock of such concern, it shall be lawful for the Licensee to acquire stock pursuant to said options and warrants (1) up to the full amount of any funds disbursed and (2) up to 25 percent of the undisbursed portion of the commitment as of the termination date thereof. The amount referred to in subparagraph (2) of this paragraph shall, for the purposes of § 107.501(k), be deemed to constitute equity capital provided by the Licensee.

4. By deleting § 107.713 *Common tenancy,* in its entirety, and substituting a new § 107.713. As amended, § 107.713 would read as follows:

§ 107.713 Common tenancy.

(a) A Licensee shall not establish or maintain an office or place of doing business which is located in the same physical premises or place of business of any other Licensee. A Licensee shall not have a common private entrance or a private connecting door or entrance with any other Licensee. Nothing contained herein shall prevent two or more Licensees from occupying space in the same office building.

(b) Licensees employing a common general manager pursuant to § 107.704 (c) (5) may apply to SBA for an exemption from the provisions of this section.

Dated: October 13, 1964.

EUGENE P. FOLEY,
Administrator.

[F.R. Doc. 64-10663; Filed, Oct. 16, 1964; 8:50 a.m.]

Notices

DEPARTMENT OF AGRICULTURE

Agricultural Stabilization and Conservation Service

[Amdt. 3]

ORGANIZATION AND FUNCTIONS

Delegations of Authority

Paragraph II 4, 5, 6 of 28 F.R. 4368 dated May 2, 1963, is amended to read 5, 6, and 7, respectively.

Paragraph II4 of 28 F.R. 4368 is added as follows: "4. Producer Associations Division."

Paragraph III D, E, F of 28 F.R. 4368 dated May 2, 1963, is amended to read E, F, and G, respectively.

Paragraph IIID of 28 F.R. 4368 dated May 2, 1963, is added as follows:

D. *Producer Associations Division.* The Producer Association Division, reporting to the Administrator, is responsible for planning, directing and coordinating operational programs and procedures pertaining to peanut, tobacco and naval stores commodity programs of CCC carried out through producer associations. It determines whether producer associations meet requirements to handle CCC loans; negotiates terms and conditions of contracts and agreements; provides direction, leadership and coordination of CCC aspects of producer association activities.

Signed at Washington, D.C., this 6th day of October 1964.

H. D. GODFREY,
Administrator, Agricultural Stabilization and Conservation Service.

Approved: October 13, 1964.

CHARLES S. MURPHY,
Acting Secretary.

[F.R. Doc. 64-10643; Filed, Oct. 16, 1964; 8:49 a.m.]

DEPARTMENT OF COMMERCE

Bureau of International Commerce

[File No. 24-63]

MOENS & CO. AND MARCEL MOENS

Order Temporarily Denying Export Privileges

In the matter of Moens & Company, Marcel Moens, 141 Turnhoutsebaan, Schilde, Antwerp, Belgium, File No. 24-63; respondents.

The Director, Investigations Division, Office of Export Control, Buerau of International Commerce, U.S. Department of Commerce, pursuant to the provisions of § 382.11 of the Export Regulations (Title 15, Chapter III, Subchapter B, Code of Federal Regulations), has applied to the Compliance Commissioner for an order temporarily denying all export privileges to the above-named respondents. It was requested that the order remain in effect for a period of sixty days pending continued investigation into the facts and transactions giving rise to the application and the commencement of such proceedings as may be deemed proper under the law against said respondent.

The Compliance Commissioner has reviewed the application and the evidence presented in support thereof and has submitted his report, together with his recommendation that the application be granted and that a temporary denial order be issued for sixty days.

The recommendation of the Compliance Commissioner has been considered. The evidence presented shows that Moens & Company is a dealer in agricultural equipment and has a place of business in Schilde, Antwerp, Belgium, and that Marcel Moens is the individual primarily responsible for the operations of said business; that a number of items of U.S.-origin agricultural equipment, some of advanced design, have been exported from Canada to Antwerp, consigned to said Moens & Company; and that additional items of U.S.-origin of a similar nature are scheduled to be exported from Canada to said Moens & Company in the near future. On the evidence presented there is reasonable basis to believe that said commodities are ultimately intended to be delivered to a Soviet-bloc destination in contravention of the U.S. Export Control Act and regulations thereunder, and that the above-named respondents are knowingly participating in a scheme to reexport said commodities from Belgium whereby said illegal purpose will be accomplished. There is also reasonable basis to believe that reexport of said commodities from Belgium is imminent and that a temporary denial order will prevent such reexportation. I find that an order temporarily denying export privileges is reasonably necessary for the protection of the public interest and national security.

Accordingly, it is hereby ordered:

I. All outstanding validated export licenses in which respondents appear or participate in any manner or capacity are hereby revoked and shall be returned forthwith to the Bureau of International Commerce for cancellation.

II. The respondents, their successors or assigns, partners, directors, representatives, agents, and employees hereby are denied all privileges of participating, directly or indirectly, in any manner or capacity, in any transaction involving commodities or technical data exported from the United States in whole or in part, or to be exported, or which are otherwise subject to the Export Regulations. Without limitation of the generality of the foregoing, participation prohibited in any such transaction, either in the United States or abroad, shall include participation, directly or indirectly, in any manner or capacity: (a) As a party or as a representative of a party to any validated export license application; (b) in the preparation or filing of any export license application or reexportation authorization, or any document to be submitted therewith; (c) in the obtaining or using of any validated or general export license or other export control document; (d) in the carrying on of negotiations with respect to, or in the receiving, ordering, buying, selling, delivering, storing, using, or disposing of any commodities or technical data in whole or in part exported or to be exported from the United States; and (e) in the financing, forwarding, transporting, or other servicing of such commodities or technical data.

III. Such denial of export privileges shall extend not only to the respondents, but also to their agents and employees and to any successor and to any person, firm, corporation, or business organization with which they now or hereafter may be related by affiliation, ownership, control, position of responsibility, or other connection in the conduct of trade or services connected therewith.

IV. This order shall take effect forthwith and shall remain in effect for a period of sixty days from the date hereof, unless it is hereafter extended, amended, modified, or vacated in accordance with the provisions of the U.S. Export Regulations.

V. No person, firm, corporation, partnership, or other business organization, whether in the United States or elsewhere, without prior disclosure to and specific authorization from the Bureau of International Commerce, shall do any of the following acts, directly or indirectly, or carry on negotiations with respect thereto, in any manner or capacity, on behalf of or in any association with the respondents or any related party, or whereby the respondents or related party may obtain any benefit therefrom or have any interest or participation therein, directly or indirectly: (a) Apply for, obtain, transfer, or use any license, shipper's export declaration, bill of lading, or other export control document relating to any exportation, reexportation, transshipment, or diversion of any commodity or technical data exported or to be exported from the United States, by, to, or for any such respondent or related party denied export privileges; or (b) order, buy, receive, use, sell, deliver, store, dispose of, forward, transport, finance, or otherwise service or participate in any exportation, reexportation, transshipment, or diversion of any commodity or technical data exported or to be exported from the United States.

VI. A copy of this order shall be served upon the respondents.

VII. In accordance with the provisions of § 382.11(c) of the Export Regulations, the respondents may move at any time to vacate or modify this temporary denial order by filing an appropriate motion

therefor, supported by evidence, with the Compliance Commissioner and may request an oral hearing thereon which, if requested, shall be held before the Compliance Commissioner in Washington, D.C., at the earliest convenient date.

This order shall become effective forthwith.

Dated: October 12, 1964.

FORREST D. HOCKERSMITH,
Director,
Office of Export Control.

[F.R. Doc. 64-10626; Filed, Oct. 16, 1964; 8:47 a.m.]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

DELMONICO FOODS, INC.

Macaroni and Spaghetti Deviating From Identity Standard; Extension of Temporary Permit To Cover Market Testing

Pursuant to § 10.5(j) of Title 21 of the Code of Federal Regulations concerning temporary permits to facilitate market testing of foods varying from the requirements of standards of identity promulgated pursuant to section 401 of the Federal Food, Drug, and Cosmetic Act, notice is given that an extension of the temporary permit issued to Delmonico Foods, Inc., Tampa, Fla., has been granted. This permit covers interstate marketing tests of macaroni and spaghetti deviating from the requirements of the standard for these foods (21 CFR 16.1). Glyceryl monostearate will be added to the products in a quantity not to exceed 2 percent by weight of the farinaceous ingredient. The labels to be used will state "glyceryl monostearate added." This permit expires April 1, 1965.

Dated October 13, 1964.

GEO. P. LARRICK,
Commissioner of Food and Drugs.

[F.R. Doc. 64-10630; Filed, Oct. 16, 1964; 8:48 a.m.]

SHERWIN-WILLIAMS CO.

Notice of Filing of Petition Regarding Food Additives Resinous and Polymeric Coatings

Pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786; 21 U.S.C. 348(b)(5)), notice is given that a petition (FAP 5B1513) has been filed by The Sherwin-Williams Company, 10909 Cottage Grove Avenue, Chicago, Ill., 60628, proposing that paragraph (b)(3)(xxxiii) of § 121.2514 *Resinous and polymeric coatings* be amended by inserting alphabetically in the list of miscellaneous materials the item "Caster oil, hydrogenated."

Dated: October 12, 1964.

MALCOLM R. STEPHENS,
Assistant Commissioner for Regulations.

[F.R. Doc. 64-10631; Filed, Oct. 16, 1964; 8:48 a.m.]

CIVIL AERONAUTICS BOARD

[Docket No. 15621]

KENTING AVIATION LTD.

Notice of Hearing

Application of Kenting Aviation Limited for a Foreign Air Carrier Permit, issued pursuant to section 402 of the Federal Aviation Act of 1958, as amended, to perform operations of a casual, occasional, or infrequent nature, in common carriage, into the United States.

Notice is hereby given, pursuant to the provisions of the Federal Aviation Act of 1958, as amended, that a hearing in the above-entitled matter is assigned to be held on November 5, 1964, at 10:00 a.m., e.s.t., in Room 701, Universal Building, Connecticut and Florida Avenues NW., Washington, D.C., before Examiner Joseph L. Fitzmaurice.

Dated at Washington, D.C., October 14, 1964.

[SEAL] FRANCIS W. BROWN,
Chief Examiner.

[F.R. Doc. 64-10638; Filed, Oct. 16, 1964; 8:49 a.m.]

[Docket No. 13795 etc.]

SUPPLEMENTAL AIR SERVICE PROCEEDING

Notice of Hearing

Notice is hereby given, pursuant to the provisions of the Federal Aviation Act of 1958, as amended, that a hearing in the above-entitled proceeding is assigned to be held on November 17, 1964, at 10 a.m., local time, in Room 1027, Universal Building, 1825 Connecticut Avenue NW., Washington, D.C., before Examiner Robert L. Park.

For information concerning the issues involved and other details in this proceeding, interested persons are referred to Board orders E-20573, dated March 13, 1964, E-20747, dated April 27, 1964, and E-20902, dated June 5, 1964, the prehearing conference report served June 2, 1964, the supplemental prehearing conference report served June 12, 1964, and other documents which are in the docket of this proceeding on file in the Docket Section of the Civil Aeronautics Board.

Dated at Washington, D.C., October 14, 1964.

[SEAL] ROBERT L. PARK,
Hearing Examiner.

[F.R. Doc. 64-10639; Filed, Oct. 16, 1964; 8:49 a.m.]

FEDERAL COMMUNICATIONS COMMISSION

[Docket Nos. 15299, 15300; FCC 64M-1001]

GREAT NORTHERN BROADCASTING SYSTEM AND MIDWESTERN BROADCASTING CO.

Order Continuing Hearing

In re applications of Robert L. Greaige and Roderick C. Maxson, d/b as Great Northern Broadcasting System, Traverse City, Mich., Docket No. 15299, File No. BPH-3982; Midwestern Broadcasting Company, Traverse City, Mich., Docket No. 15300, File No. BPH-4079; for construction permits.

It is ordered, This 9th day of October 1964, that the hearing is rescheduled from October 16 to October 30, 1964, at 9:00 a.m.

Released: October 12, 1964.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] BEN F. WAPLE,
Secretary.

[F.R. Doc. 64-10634; Filed, Oct. 16, 1964; 8:48 a.m.]

[Docket No. 15571; FCC 64M-1009]

INDIAN RIVER BROADCASTING CO. (WIRA)

Order Continuing Hearing

In re application of Indian River Broadcasting Company (WIRA), Fort Pierce, Fla., Docket No. 15571, File No. BP-15740; for construction permit.

Pursuant to a prehearing conference as of this date: *It is ordered,* This 13th day of October 1964, that the exchange of the engineering exhibits herein shall be accomplished on or before December 3, 1964; that the notification date for the witnesses desired for cross-examination shall be December 10, 1964; and that the hearing herein scheduled for October 14, 1964, be and the same is hereby rescheduled for December 17, 1964, 10:00 a.m., in the Commission's Offices, Washington, D.C.

Released: October 13, 1964.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] BEN F. WAPLE,
Secretary.

[F.R. Doc. 64-10635; Filed, Oct. 16, 1964; 8:48 a.m.]

[Docket Nos. 15482, 15483; FCC 64M-1002]

SOUTH JERSEY TELEVISION CABLE CO.

Order Continuing Hearing

In re application of South Jersey Television Cable Co., Docket No. 15482, File No. 17325-IB-114X; Docket No. 15483, File No. 17326-IB-114X; for operational fixed stations in the business radio service.

The Hearing Examiner having under consideration a petition filed on October 8, 1964, by South Jersey Television Cable Co., requesting that the hearing in the above-entitled proceeding presently scheduled to commence on October 12, 1964, be continued indefinitely, pending action by the Commission on a motion to withdraw from such proceeding, filed by Francis J. Matrangola, the party respondent in the proceeding; and

It appearing, that the applications of South Jersey Television Cable Co. were designated for hearing because of a petition to deny such applications filed by Francis J. Matrangola on April 13, 1964; and

It further appearing, that there is now pending before the Commission en banc a motion to withdraw such petition to deny, filed by Matrangola on September 21, 1964, and a grant of such motion to withdraw may render a hearing in this proceeding unnecessary; and

It further appearing, that counsel for the other parties have informally agreed to an immediate consideration of the instant petition for continuance and that under the circumstances good cause has been shown for the grant thereof;

It is ordered, This 9th day of October 1964, that the hearing in the above-entitled proceeding now scheduled to commence on October 12, 1964, be and it is hereby continued until further order.

Released: October 12, 1964.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] BEN F. WAPLE,
Secretary.

[F.R. Doc. 64-10636; Filed, Oct. 16, 1964; 8:48 a.m.]

[Docket No. 15457; FCC 64M-1010]

TRIANGLE PUBLICATIONS, INC. (RADIO AND TELEVISION DIVISION)

Order Continuing Hearing

In re application of Triangle Publications, Inc. (Radio and Television Division), Johnstown, Pa., Docket No. 15457, File No. BPTTV-12; for construction permit for new VHF television broadcast translator station.

The Hearing Examiner having under consideration oral, telephonic communication, from counsel for the applicant in the above-entitled proceeding, on October 12, 1964, informing the Examiner that a petition for the dismissal of the application would be filed with the Commission today (with courtesy copy to the presiding officer); and the scheduled date for commencement of the hearing, October 14;

It appearing, that the parties, their attorneys, the Hearing Examiner, and the court reporter, ought not to be inconvenienced by having to present themselves in the hearing room tomorrow if the applicant carries out its intention to dismiss its application, and that the hearing room, under the circumstances should be released for other, more useful purposes;

It is ordered, This 13th day of October 1964, on the Hearing Examiner's own motion, that the hearing, which is now scheduled to commence at 10 a.m. on Wednesday, October 14, 1964, at the Commission's offices, Washington, D.C., is hereby continued to Wednesday, December 2, 1964; at the same time and place, subject, however, to further order in the premises.

Released: October 13, 1964.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] BEN F. WAPLE,
Secretary.

[F.R. Doc. 64-10637; Filed, Oct. 16, 1964; 8:49 a.m.]

FEDERAL MARITIME COMMISSION

FERN LINE AND PACIFIC/INDONESIAN CONFERENCE

Notice of Agreements Filed for Approval

Notice is hereby given that the following Agreements have been filed with the Commission for approval pursuant to section 15 of the Shipping Act, 1916, as amended (39 Stat. 733, 75 Stat. 763, 46 U.S.C. 814).

Interested parties may inspect and obtain a copy of the agreement(s) at the Washington office of the Federal Maritime Commission, 1321 H Street NW., Room 301; or may inspect agreements at the offices of the District Managers, New York, N.Y., New Orleans, La., and San Francisco, Calif. Comments with reference to an agreement including a request for hearing, if desired, may be submitted to the Secretary, Federal Maritime Commission, Washington, D.C., 20573, within 20 days after publication of this notice in the FEDERAL REGISTER. A copy of any such statement should also be forwarded to the party filing the agreement (as indicated hereinafter), and the comments should indicate that this has been done.

Notice of agreement filed for approval by:

Mr. R. E. Spaulding, Secretary
Pacific/Indonesian Conference
465 California Street
San Francisco 4, Calif.

Agreement 6060-E between Fern Line and Pacific/Indonesian Conference cancels and supersedes Agreement No. 6060-C, and provides for associate membership of the Fern Line in the Pacific/Indonesian Conference under the terms and conditions set forth in the new associate membership agreement.

Dated: October 13, 1964.

By order of the Federal Maritime Commission.

THOMAS LISI,
Secretary.

[F.R. Doc. 64-10616; Filed, Oct. 16, 1964; 8:47 a.m.]

FERN LINE AND PACIFIC-STRAITS CONFERENCE

Notice of Agreements Filed for Approval

Notice is hereby given that the following Agreements have been filed with the Commission for approval pursuant to section 15 of the Shipping Act, 1916, as amended (39 Stat. 733, 75 Stat. 763, 46 U.S.C. 814).

Interested parties may inspect and obtain a copy of the agreement(s) at the Washington office of the Federal Maritime Commission, 1321 H Street NW., Room 301; or may inspect agreements at the offices of the District Managers, New York, N.Y., New Orleans, La., and San Francisco, Calif. Comments with reference to an agreement including a request for hearing, if desired, may be submitted to the Secretary, Federal Maritime Commission, Washington, D.C., 20573, within 20 days after publication of this notice in the FEDERAL REGISTER. A copy of any such statement should also be forwarded to the party filing the agreement (as indicated hereinafter), and the comments should indicate that this has been done.

Notice of agreement filed for approval by:

Mr. R. E. Spaulding, Secretary, Pacific-Straits Conference, 465 California Street, San Francisco 4, Calif.

Agreement 5680-M between Fern Line and Pacific-Straits Conference cancels and supersedes Agreement No. 5680-G, and provides for associate membership of the Fern Line in the Pacific-Straits Conference under the terms and conditions set forth in the new associate membership agreement.

Dated: October 13, 1964.

By order of the Federal Maritime Commission.

THOMAS LISI,
Secretary.

[F.R. Doc. 64-10617; Filed, Oct. 16, 1964; 8:47 a.m.]

RED SEA AND GULF OF ADEN/U.S. ATLANTIC AND GULF RATE AGREEMENT

Notice of Agreements Filed for Approval

Notice is hereby given that the following agreements have been filed with the Commission for approval pursuant to section 15 of the Shipping Act, 1916, as amended (39 Stat. 733, 75 Stat. 763, 46 U.S.C. 814).

Interested parties may inspect and obtain a copy of the agreement(s) at the Washington office of the Federal Maritime Commission, 1321 H Street NW., Room 301; or may inspect agreements at the offices of the District Managers, New York, N.Y., New Orleans, La., and San Francisco, Calif. Comments with reference to an agreement including a request for hearing, if desired, may be submitted to the Secretary, Federal Maritime Commission, Washington, D.C.,

20573, within 20 days after publication of this notice in the FEDERAL REGISTER. A copy of any such statement should also be forwarded to the party filing the agreement (as indicated hereinafter), and the comments should indicate that this has been done.

Notice of agreement filed for approval by:

Mr. J. C. Pendleton, Secretary, Red Sea and Gulf of Aden/U.S. Atlantic and Gulf Rate Agreement, Eleven Broadway, New York 4, N.Y.

Agreement 8558–2 between member lines of the Red Sea and Gulf of Aden/U.S. Atlantic and Gulf Rate Agreement, modifies the basic agreement (8558, as amended) to provide for the inclusion of procedures relating to Admission, Withdrawal and Expulsion pursuant to General Order 9 (46 CFR Part 523).

Dated: October 13, 1964.

By order of the Federal Maritime Commission.

THOMAS LISI,
Secretary.

[F.R. Doc. 64–10618; Filed, Oct. 16, 1964; 8:47 a.m.]

[Docket No. 1207]

SEATRAIN LINES, INC.

Application of Rates on Shipments in Railroad Cars; Notice of Investigation and Suspension

It appearing, that there have been filed with the Federal Maritime Commission by Seatrain Lines, Inc. (Seatrain), tariff schedules seeking to establish tariff provisions which would permit the substitution of rail cars for trailers or containers at the rates published for such trailers or containers, between U.S. Atlantic and Gulf ports, on the one hand and ports in Puerto Rico on the other to become effective October 5, 1964, designated as follows:

SEATRAIN LINES, INC.

Outward Freight Tariff No. 1, FMC–F No. 1
4th Revised Page 70 (Item, No. 305)
"Application of Rates on Shipments in Railroad Cars"
and
Homeward Freight Tariff No. 3, FMC–F No. 3
3d Revised Page 25–B (Item No. 410)
"Application of Rates on Shipments in Railroad Cars"

It further appearing, that upon consideration of the said schedules and protests and replies thereto there is reason to believe that the said tariff provisions if permitted to become effective, would result in rates, charges, rules, regulations, and/or practices which would be unjust, unreasonable, or otherwise unlawful in violation of the Shipping Act, 1916, or the Intercoastal Shipping Act, 1933;

It further appearing, that, the Commission is of the opinion that the new tariff provisions should be made the subject of a public investigation and hearing to determine whether they are unjust, unreasonable, or otherwise unlawful under the Shipping Act, 1916, or the Intercoastal Shipping Act, 1933;

It further appearing, that the effective date of the said provisions should be suspended pending such investigation;

It further appearing, that there is a question of the applicable rate to be assessed for the transportation of a commodity whose rate is predicated upon "shipper load/consignee unload" when such commodity actually moves via Seatrain's rail car service with Seatrain's Puerto Rican stevedores performing the car loading and/or unloading of rail cars;

Now therefore it is ordered, That an investigation be and it is hereby, instituted into and concerning the lawfulness of Item Nos. 305 and 410 in the said schedules with a view to making such findings and orders in the premises as the facts and circumstances shall warrant; and the investigation hereby instituted shall include an inquiry into Seatrain's practices insofar as they pertain to rail car movements at trailer or container rates predicated upon "shipper load/consignee unload" within the Commonwealth of Puerto Rico for the purpose of determining whether these practices are in violation of sections 16, 17, and 18(a) of the Shipping Act, 1916 and section 2 of the Intercoastal Shipping Act, 1933;

It is further ordered, That Item Nos. 305 and 410 published on the aforementioned revised pages be, and they are hereby suspended and that the use thereof be deferred to and including February 4, 1965, unless otherwise authorized by the Commission, and that the rates, fares, charges, rules, regulations, and/or practices heretofore in effect, and which were to be changed by the suspended matter shall remain in effect during the period of suspension;

It is further ordered, That no change shall be made in the matter hereby suspended nor the matter which is continued in effect as a result of such suspension until the period of suspension has expired, or until this investigation and suspension proceeding has been disposed of, whichever first occurs unless otherwise authorized by the Commission;

It is further ordered, That there shall be filed immediately with the Commission by Seatrain Lines, Inc., a consecutively numbered supplement to each of the aforesaid tariffs, which supplement shall bear no effective date, shall reproduce the portion of this order wherein the suspended matter is described, and shall state that the aforesaid rates are suspended and may not be used until the 5th day of February 1965, unless otherwise authorized by the Commission; and that the rates and charges heretofore in effect, and which were to be changed by the suspended matter shall remain in effect during the period of suspension, and neither the matter suspended, nor the matter which is continued in effect as a result of such suspension, may be changed until the period of suspension has expired or until this investigation and suspension proceeding has been disposed of, whichever first occurs, unless otherwise authorized by the Commission;

It is further ordered, That copies of this order shall be filed with the said tariff schedules in the Bureau of Domestic Regulation of the Federal Maritime Commission;

It is further ordered, That (I) the investigation herein ordered be assigned for public hearing by the Chief Examiner, before an examiner of the Commission's Office of Hearing Examiners, at a date and place to be announced; (II) Seatrain Lines, Inc. be, and it is hereby made respondent in this proceeding; (III) a copy of this order shall forthwith be served upon said respondent and protestants herein; (IV) the said respondent and protestants be duly notified of the time and place of the hearing herein ordered; and (V) this order and notice of the said hearing be published in the FEDERAL REGISTER.

All persons (including individuals, corporations, associations, firms, partnerships, and public bodies) having an interest in this proceeding and desiring to intervene therein, should notify the Secretary of the Commission promptly and file petitions for leave to intervene in accordance with Rule 5(n) (46 CFR 502.73), with copy to respondent.

By the Commission, October 1, 1964.

[SEAL] THOMAS LISI,
Secretary.

[F.R. Doc. 64–10619; Filed, Oct. 16, 1964; 8:47 a.m.]

FEDERAL RESERVE SYSTEM

CLAYTON BANCSHARES CORP.

Order Denying Application Under Bank Holding Company Act

In the matter of the application of Clayton Bancshares Corporation for approval of action to become a bank holding company through the acquisition of voting shares of Bank of Crestwood, Crestwood, Missouri, and Hampton Bank of St. Louis, St. Louis, Missouri.

There has come before the Board of Governors, pursuant to section 3(a)(1) of the Bank Holding Company Act of 1956 (12 U.S.C. 1842(a)(1)) and § 222.4 (a)(1) of Federal Reserve Regulation Y (12 CFR 222.4(a)(1)), an application by Clayton Bancshares Corporation, Clayton, Missouri, for the Board's prior approval of action whereby Applicant would become a bank holding company through the acquisition of 58.24 per cent of the voting shares of Bank of Crestwood, Crestwood, Missouri, and 55.98 per cent of the voting shares of Hampton Bank of St. Louis, St. Louis, Missouri.

As required by section 3(b) of the Act, the Board notified the Commissioner of Finance for the State of Missouri of the receipt of the application and requested his views and recommendation. The Commissioner replied but declined to express any views or to make a recommendation respecting the application.

Notice of Receipt of Application was published in the FEDERAL REGISTER on April 7, 1964 (29 F.R. 4897), which provided an opportunity for the filing of comments and views regarding the proposed acquisition, and the time for filing such comments and views has expired

and all comments and views filed with the Board have been considered by it.

It is hereby ordered, For the reasons set forth in the Board's Statement[1] of this date, that the said application be and hereby is denied.

Dated at Washington, D.C., this 13th day of October 1964.

By order of the Board of Governors.[2]

[SEAL] MERRITT SHERMAN, *Secretary.*

[F.R. Doc. 64-10601; Filed, Oct. 16, 1964; 8:45 a.m.]

SECURITIES AND EXCHANGE COMMISSION

[File Nos. 24S-1965, 24S-1912]

OREGON KING CONSOLIDATED MINES, INC.

Notice and Order for Hearing

OCTOBER 12, 1964.

I. Oregon King Consolidated Mines, Inc. (issuer), 521 Failing Building, Portland 4, Oregon, filed on February 7, 1963, a notification and offering circular relating to a proposed public offering of 100,000 shares of its $1 par value common stock at $1 per share for an aggregate amount of $100,000. The offering commenced on March 22, 1963, and a final Form 2-A, report of sales, filed on April 23, 1964, reflected that all shares had been sold by December 22, 1963. Subsequently, the issuer filed with the Commission on August 11, 1964, a second notification and offering circular relating to a proposed offering of $100,000 of 6 percent convertible debentures for the purpose of obtaining a further exemption under Regulation A for said debentures. This offering has not commenced.

II. The Commission, on September 9, 1964, issued an order pursuant to Rule 261 of the general rules and regulations of the Securities Act of 1933, as amended, temporarily suspending the issuer's exemption under Regulation A, and affording to any person having any interest therein an opportunity to request a hearing. A written request for a hearing has been received by the Commission.

The Commission deems it necessary and appropriate that a hearing be held for the purpose of determining whether it should vacate the temporary suspension order or enter an order of permanent suspension in this matter.

It is hereby ordered, Pursuant to Rule 261 of the general rules and regulations under the Securities Act of 1933, as amended, that a hearing be held on November 2, 1964, at 10:00 a.m., in Room 205 of the U.S. Court House located at Southwest Broadway and Madison, Portland, Oregon, with respect to the matters set forth in Section II of the order dated September 9, 1964, temporarily suspending the issuer's exemption under Regulation A, without prejudice, however, to the specification of additional issues which may be presented in the proceedings.

III. *It is further ordered,* That Warren E. Blair, or any officer or officers of the Commission designated by it for that purpose, shall preside at the hearing; that any officer or officers so designated to preside at any such hearing are hereby authorized to exercise all the powers granted to the Commission under sections 19(b), 21 and 22(c) of the Securities Act of 1933, as amended, and to hearing officers under the Commission's rules of practice.

It is further ordered, That the Secretary of the Commission shall serve a copy of this order by registered mail on Oregon King Consolidated Mines, Inc., and that notice of the entering of this order shall be given to all persons by general release of the Commission and by publication in the FEDERAL REGISTER. Any person who desires to be heard or otherwise wishes to participate in the hearing shall file with the Commission on or before October 30, 1964, a request relative thereto as provided in Rule 9(c) of the Commission's rules of practice.

By the Commission.

[SEAL] ORVAL L. DUBOIS, *Secretary.*

[F.R. Doc. 64-10610; Filed, Oct. 16, 1964; 8:46 a.m.]

INTERSTATE COMMERCE COMMISSION

[Notice 1063]

MOTOR CARRIER TRANSFER PROCEEDINGS

OCTOBER 14, 1964.

Synopses of orders entered pursuant to section 212(b) of the Interstate Commerce Act, and rules and regulations prescribed thereunder (49 CFR Part 179), appear below:

As provided in the Commission's special rules of practice any interested person may file a petition seeking reconsideration of the following numbered proceedings within 20 days from the date of publication of this notice. Pursuant to section 17(8) of the Interstate Commerce Act, the filing of such a petition will postpone the effective date of the order in that proceeding pending its disposition. The matters relied upon by petitioners must be specified in their petitions with particularity.

No. MC-FC 67019. By order of October 9, 1964, the Transfer Board approved the transfer to Mary A. Watts, Philadelphia, Pa., of permit in No. MC 89040, issued March 23, 1940, to Edward A. Watts, Philadelphia, Pa., authorizing the transportation of: Set-up paper boxes, from Philadelphia, Pa., to Asbury Park and Atlantic City, N.J. Stanley L. Kubacki, 1407 Finance Bldg., Philadelphia, Pa., 19102, attorney for applicants.

No. MC-FC 67082. By order of October 9, 1964, the Transfer Board approved the transfer to Kenneth Buchanan Trucking, Inc., Marietta, Ohio, of certificate in No. MC 101053, issued December 31, 1959, to Kenneth Buchanan, Marietta, Ohio, authorizing the transportation of: Such commodities as are usually handled by dump truck and which can be unloaded by dumping, between points in Ohio, Pennsylvania, and West Virginia within 50 miles of Weirton, W. Va., and, various named commodities usually transported in dump trucks, from, to, or between, specified points in Ohio and West Virginia. Earl N. Merwin, 85 East Gay Street, Columbus, Ohio, 43215, attorney for applicants.

No. MC-FC 67148. By order of October 8, 1964, the Transfer Board approved the transfer to Midland Park Moving & Storage Limited, A Limited Partnership, Midland Park, N.J., of Certificate in No. MC 18025, issued September 11, 1942, to Walter Gus Lehmann, doing business as Walter Lehmann Movers, Ridgewood, N.J., authorizing the transportation of: Household goods, between points in Bergen and Passaic Counties, N.J., on the one hand, and, on the other, points in New York. John M. Zachara, Post Office Box 2860, Paterson, N.J., 07509, attorney for applicants.

No. MC-FC 67169. By order of October 8, 1964, the Transfer Board approved the transfer to Miller-Illinois, Inc., Kansas City, Mo., of a portion of the operating rights in the certificates in Nos. MC 92983, MC 92983 Sub 22, MC 92983 Sub 30, MC 92983 Sub 146, and MC 92983 Sub 223, and the entire operating rights in the certificates in Nos. MC 92983 Sub 26 and MC 92983 Sub 29, issued June 13, 1949, December 29, 1949, June 27, 1952, December 11, 1956, June 26, 1958, April 25, 1960, and June 15, 1950, respectively, to Eldon Miller, Inc., Kansas City, Mo., authorizing the transportation of: Livestock, agricultural commodities, except in bulk, feed except in bulk, farm machinery, hardware, and building materials, except in bulk, between Kalona, Iowa, and Chicago, Ill., as specified, serving certain intermediate and off-route points; livestock, windmills, windmill parts, and petroleum products, between Riverside, Iowa, and Chicago, Ill., serving intermediate and off-route points as specified, feed except in bulk, from Chicago, Peru, Galesburg, Sullivan, Danville, Ill., St. Joseph, Mo., and Omaha, Nebr., to points as specified in Iowa, and between the plant site of Protein Blenders, Inc., near Iowa City, Iowa, and points in Kansas, Missouri, Minnesota, Nebraska, and those in Illinois as specified, farm implements, from Rock Falls, Rock Island, Sandwich, and Rockford, Ill., to Lowden, Iowa, and points in Iowa within 40 miles of Lowden; coal, from and to points as specified in Illinois and Iowa; hides, from Iowa City, Iowa, and points within 1 mile, to Milwaukee, Wis.; livestock from and to points as specified in Iowa and those in Missouri, Nebraska,

[1] Filed as part of the original document. Copies available upon request to the Board of Governors of the Federal Reserve System, Washington, D.C., 20551, or to the Federal Reserve Bank of St. Louis. Dissenting Statement of Governor Mitchell also filed as part of the original document and available upon request.

[2] Voting for this action: Chairman Martin, and Governors Balderston, Mills, and Robertson. Voting against this action: Governor Mitchell. Absent and not voting: Governors Shepardson and Daane.

Illinois, Wisconsin, and Kansas; general commodities, excluding household goods, commodities in bulk and other specified commodities, between points in the Chicago, Ill., commercial zone, and from Chicago to Lowden, Iowa, and points in Iowa within 40 miles; heavy machinery, contractors' equipment, materials and supplies except in bulk, and commodities which because of size or weight require the use of special equipment or special handling, between Indianapolis, Ind., on the one hand, and, on the other, points in Iowa.

Heavy machinery, contractors' equipment, materials and supplies except in bulk, used buildings, and commodities which because of size or weight require the use of special equipment or special handling; between points in Iowa, on the one hand, and, on the other, points in Kansas as specified and those in Illinois, Wisconsin, Minnesota, Nebraska, and Missouri; machinery and contractors' equipment, which because of size or weight, require the use of special equipment or special handling, between points in Iowa, Illinois, Wisconsin, Minnesota, Nebraska, Kansas, and Missouri, within 300 miles of Ames, Iowa; building materials, roofing, and roofing materials, except in bulk, from Lockport, Ill., to points in Iowa; contractors' equipment and related contractors' materials and supplies, incidental to the transportation of such equipment, commodities requiring special handling or the use of special equipment, internal combustion engines and parts thereof, and iron and steel casting, between points in Iowa, on the one hand, and, on the other, points in Arkansas, Kentucky, Ohio, Tennessee, and those in Indiana and Michigan as specified; highway and bridge construction and maintenance machinery and equipment, between points in Illinois, Iowa, Minnesota, Missouri, and Wisconsin as specified; iron and steel castings of over 300 lbs., structural and reinforcing steel, internal combustion engines, generators, and parts of and accessories for highway and bridge construction and maintenance machinery and equipment, between points in Iowa, Illinois, and those in Missouri, Minnesota, and Wisconsin as specified; culvert pipe, from Clinton, Iowa to points in Minnesota and Wisconsin as specified, Alum, except in bulk, from East St. Louis, Ill., and points within 5 miles, to Iowa City, Iowa; lime, except in bulk, from Mosher, Mo., to Iowa City, Iowa; Salt, except in bulk, from Hutchinson and Kanopolis, Kans., and points within 5 miles of each, to Iowa City, Iowa; feed, except in bulk, from Cedar Rapids, Iowa, to Muscatine, Iowa; petroleum and petroleum products, as described, in containers, from Berwyn, Ill., to points in North Dakota and South Dakota, and empty packages and containers in the reverse direction. Vernon V. Baker, 1411 K Street NW., Washington, D.C., 20005, attorney for applicants.

[SEAL] HAROLD D. McCOY,
Secretary.

[F.R. Doc. 64–10627; Filed, Oct. 16, 1964; 8:47 a.m.]

CUMULATIVE CODIFICATION GUIDE—OCTOBER

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PART II

FEDERAL REGISTER

VOLUME 29 NUMBER 204

Washington, Saturday, October 17, 1964

Department of Health, Education, and Welfare

Food and Drug Administration

DRUGS

Notice of Proposed Rule Making

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Parts 146, 148i, 148m, 148n, 148p, 148r]

NEOMYCIN SULFATE, TRIACETYLOLEANDOMYCIN, OXYTETRACYCLINE, POLYMYXIN B SULFATE, TYROTHRICIN

Proposed Certification Procedure and Tests and Methods of Assay

The Commissioner of Food and Drugs, in accordance with procedure established in the Federal Food, Drug, and Cosmetic Act (sec. 507, 59 Stat. 463 as amended; 21 U.S.C. 357) and under the authority delegated to him by the Secretary of Health, Education, and Welfare (21 CFR 2.90; 29 F.R. 471), proposes to issue regulations providing for certification and tests and methods of assay for certain antibiotic and antibiotic-containing drugs.

Before enactment of the "Drug Amendments of 1962" these drugs had been cleared for marketing under the safety provisions of the new drug section of the Federal Food, Drug, and Cosmetic Act. The "Drug Amendments of 1962" provided for certification of the drugs under the antibiotic section of the law (sec. 507). If further specified that if the new-drug approvals had not been withdrawn on the day immediately preceding the effective date (April 30, 1963), the initial issuance of regulations providing for certification of the drugs under the antibiotic section of the law (sec. 507) shall not be conditioned upon an affirmative finding of efficacy of the drugs. Accordingly the initial issuance of regulations cannot be and is not conditioned upon an affirmative finding of efficacy of the drugs involved.

The review of efficacy of the drugs covered by this proposal has not been completed. When completed it may indicate, for any of the products, no need for change, a need for modification of the regulation, or a need to revoke the regulation. Any changes that appear to be needed, based upon efficacy considerations, will be published at a later date as proposals.

A proposed regulation for tests and methods of assay and certification of oxytetracycline troches was published in the FEDERAL REGISTER of April 18, 1963 (28 F.R. 3839). Final action on the oxytetracycline troches proposal will be taken concurrently with that on the proposals in this notice and will be conditioned on the statutory requirements as set forth in the preamble of this notice.

All interested persons are hereby invited to submit written views and comments on these proposals, preferably in quintuplicate, within 30 days from the date of the publication of this notice in the FEDERAL REGISTER, addressed to the Hearing Clerk, Department of Health, Education, and Welfare, Room 5440, 330 Independence Avenue SW., Washington, D.C., 20201.

A. It is proposed to amend § 146.1 *Definitions and interpretations applicable to all certifiable antibiotic drugs* as follows by adding to paragraphs (a), (b), and (d) the following new subparagraph, and by adding the following new subdivision to paragraph (c)(2) to read as follows:

§ 146.1 Definitions and interpretations applicable to all certifiable antibiotic drugs.

(a) * * *

(20) Each of the antibiotic substances produced by the triacetylation of oleandomycin, and each of the same substances produced by any other means, is a kind of triacetyloleandomycin.

* * * * *

(b) * * *

(29) The term "triacetyloleandomycin master standard" means a specific lot of triacetyloleandomycin designated by the Commissioner as the standard of comparison in determining the potency of the triacetyloleandomycin working standard.

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(c) * * *

(2) * * *

(xxiii) The term "microgram" applied to triacetyloleandomycin means the activity (potency), calculated as the molecular equivalent of the oleandomycin base, contained in 1.2315 micrograms of the triacetyloleandomycin master standard when dried for 3 hours at 60° C. and a pressure of 5 milliliters or less.

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(d) * * *

(24) The term "triacetyloleandomycin working standard" means a specific lot of a homogenous preparation of triacetyloleandomycin.

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B. It is proposed to amend Parts 148i, 148m, 148n, 148p, and 148r by adding the following new sections:

§ 148i.13 Neomycin sulfate-hydrocortisone acetate suspension for intra-articular use.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Neomycin sulfate-hydrocortisone acetate suspension for intra-articular use contains, in each milliliter, 3.5 milligrams of neomycin and 50 milligrams of hydrocortisone acetate. It contains one or more suitable preservatives, dispersants, and buffers. It is sterile. It passes the toxicity test. Its pH is not less than 5.3 and not more than 7.0. The neomycin sulfate used conforms to the standards prescribed by § 148i.1(a)(1) (i), (iii), (vi), and (vii). Each other ingredient used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Requests for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The neomycin sulfate used in making the batch for potency, pyrogens, pH, and identity.

(*b*) The batch for potency, sterility, toxicity, and pH.

(ii) Samples required:

(*a*) The neomycin sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch:

(*1*) For all tests except sterility: A minimum of eight immediate containers.

(*2*) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(4) *Fees.* $4.00 for each immediate container or package in the samples submitted in accordance with subparagraph (3)(ii) (*a*), (*b*)(*1*), and (*c*) of this paragraph; $12.00 for all immediate containers in the sample submitted in accordance with subparagraph (3)(ii) (*b*)(*2*) of this paragraph; $24.00 for all containers in the samples submitted for any repeat sterility test, if necessary, in accordance with § 141.2(f) of this chapter.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148i.1 (b)(1), except prepare a stock solution of convenient concentration by placing an accurately measured representative portion of the sample into an appropriate-sized volumetric flask and diluting to volume with 0.1*M* potassium phosphate buffer, pH 8.0. Further dilute an aliquot of the stock solution to the proper prescribed reference concentration with 0.1*M* potassium phosphate buffer, pH 8.0. Its content of neomycin is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of milligrams of neomycin that it is represented to contain.

(2) *Sterility.* Proceed as directed in § 141.2 of this chapter, using the method described in paragraph (e)(2) of that section, except transfer 0.25 milliliter in lieu of 1.0 milliliter.

(3) *Toxicity.* Proceed as directed in § 141a.4 of this chapter, using 0.5 milliliter of a solution containing 200 micrograms (estimated) of neomycin per milliliter in sterile distilled water.

(4) *pH.* Proceed as directed in § 141a.5(b) of this chapter, using the undiluted sample.

§ 148i.17 Neomycin sulfate-polymyxin B sulfate oral solution.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Neomycin sulfate-polymyxin B sulfate oral solution contains, in each milliliter, 9.1 milligrams of neomycin and 1,000 units of polymyxin B. It contains one or more suitable flavorings, colorings, and preservatives. Its pH is not less than 6.0 and not more than 7.5. The neomycin sulfate used conforms to the standards prescribed by § 148i.1(a)(1) (i), (iv), (vi), and (vii). The polymyxin B sulfate used conforms to the standards prescribed by § 148p.1(a)(1) (i), (iv), (vi), (vii), and (ix) of this

chapter. Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Requests for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The neomycin sulfate used in making the batch for potency, toxicity, pH, and identity.

(*b*) The polymyxin B sulfate used in making the batch for potency, toxicity, pH, residue on ignition, and identity.

(*c*) The batch for neomycin content, polymyxin content, and pH.

(ii) Samples required:

(*a*) The neomycin sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The polymyxin B sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*c*) The batch: A minimum of six immediate containers.

(*d*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(4) *Fees.* $5.00 for each immediate container in the sample submitted in accordance with subparagraph (3) (ii) (*c*) of this paragraph; $4.00 for each package in the samples submitted in accordance with subparagraph (3) (ii) (*a*), (*b*), and (*d*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Neomycin content.* Proceed as directed in § 148i.1(b) (1), except prepare the sample for assay as follows: Remove an accurately measured representative portion and dilute with sufficient 0.1*M* potassium phosphate buffer, pH 8.0, to give a stock solution of convenient concentration. Further dilute with 0.1*M* potassium phosphate buffer, pH 8.0, to the proper prescribed reference concentration. Its content of neomycin is satisfactory if it is not less than 90 percent and not more than 125 percent of the number of milligrams of neomycin that it is represented to contain.

(ii) *Polymyxin content.* Remove an accurately measured representative portion and dilute with 10 percent potassium phosphate buffer, pH 6.0, to give a stock solution of convenient concentration. Further dilute in 10 percent potassium phosphate buffer, pH 6.0, to 10 units of polymyxin (estimated) per milliliter. Proceed as directed in § 148p.1(b) (1) of this chapter, except add to each concentration of the polymyxin standard curve a quantity of neomycin to yield the same concentration of neomycin as that present when the sample is diluted to contain 10 units of polymyxin per milliliter. Its content of polymyxin is satisfactory if it contains not less than 90 percent and not more than 125 percent of the number of units of polymyxin that it is represented to contain.

(2) *pH.* Proceed as directed in § 141a.5(b) of this chapter, using the undiluted sample.

§ 148i.28 Neomycin sulfate-gramicidin-hydrocortisone acetate-phenylephrine hydrochloride-thonzonium bromide-thonzylamine hydrochloride nasal solution.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Neomycin sulfate-hydrochloride-thonzonium bromide-thonzylamine hydrochloride nasal solution is a solution containing, in each milliliter, 0.66 milligram of neomycin, 0.05 milligram of gramicidin, 0.2 milligram of hydrocortisone acetate, 2.5 milligrams of phenylephrine hydrochloride, 0.5 milligram of thonzonium bromide, 10.0 milligrams of thonzylamine hydrochloride, and one or more suitable buffers, preservatives, and surfactants. Its pH is not less than 4.8 and not more than 6.0. The neomycin sulfate used conforms to the standards prescribed by § 148i.1(a) (1) (i), (iv), (vi), and (vii). The gramicidin used conforms to the standards prescribed by § 148f.1(a) (1) (i), (ii), (iv), (v), and (vi) of this chapter. Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assay on:

(*a*) The neomycin sulfate used in making the batch for potency, toxicity, pH, and identity.

(*b*) The gramicidin used in making the batch for potency, toxicity, residue on ignition, melting point, and identity.

(*c*) The batch for neomycin content, gramicidin content, and pH.

(ii) Samples required:

(*a*) The neomycin sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The gramicidin used in making the batch: 10 packages, each containing approximately 500 milligrams.

(*c*) The batch: A minimum of six immediate containers.

(*d*) In the case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(4) *Fees.* $5.00 for each immediate container in the sample submitted in accordance with subparagraph (3) (ii) (*c*) of this paragraph; $4.00 for each package in the samples submitted in accordance with subparagraph (3) (ii) (*a*), (*b*), and (*d*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Neomycin content.* Proceed as directed in § 148i.20(b) (1) (i). Its content of neomycin is satisfactory if it is not less than 90 percent and not more than 125 percent of the number of milligrams of neomycin that it is represented to contain.

(ii) *Gramicidin.* Proceed as directed in § 148i.20(b) (1) (iii). Its content of gramicidin is satisfactory if it contains not less than 90 percent and not more than 125 percent of the number of milligrams of gramicidin that it is represented to contain.

(2) *pH.* Proceed as directed in § 141a.5(b) of this chapter, using the undiluted sample.

§ 148i.31 Neomycin sulfate (commercial grade).

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Neomycin sulfate (commercial grade) is the sulfate salt of a kind of neomycin or a mixture of two or more such salts. It is so purified and dried that:

(i) Its potency is not less than 400 micrograms of neomycin per milligram on the anhydrous basis.

(ii) It passes the toxicity test.

(iii) Its moisture content is not more than 8.0 percent.

(iv) Its pH in an aqueous solution containing 33 milligrams of neomycin sulfate commercial grade per milliliter is not less than 4.0 and not more than 7.5.

(v) It gives a positive identity test for neomycin sulfate.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3(b) of this chapter. Its expiration date is 12 months.

(3) *Requests for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, toxicity, moisture, pH, and identity.

(ii) Samples required: 10 packages, each containing approximately 300 milligrams.

(4) *Fees.* $4.00 for each container submitted in accordance with subparagraph (3) (ii) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148i.1 (b) (1).

(2) *Toxicity.* Proceed as directed in § 148i.1(b) (4).

(3) *Moisture.* Proceed as directed in § 148i.1(b) (5).

(4) *pH.* Proceed as directed in § 148i.1(b) (6).

(5) *Identity.* Proceed as directed in § 148i.1(b) (7).

§ 148i.30 Neomycin sulfate (commercial grade)-aluminum chlorohydroxide cream deodorant.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Neomycin sulfate (commercial grade)-aluminum chlorohydroxide cream deodorant is neomycin sulfate (commercial grade) and aluminum chlorohydroxide in a suitable cream base. It contains, in each gram, the following:

(i) 1 milligram of neomycin and 120 milligrams of aluminum chlorohydroxide (anhydrous); or

(ii) 1.75 milligrams of neomycin and either 100 milligrams or 176 milligrams of aluminum chlorohydroxide (anhydrous).

It may also contain one or more suitable emollients, perfumes, colorings, dispersants, solubilizers, buffers, and preservatives. The neomycin sulfate (commercial grade) used conforms to the standards prescribed by § 148i.31(a)(1). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(i) On the label of the immediate container and on the outside wrapper or container, if any:

(*a*) The batch mark.

(*b*) The name and quantity of each active ingredient contained in the drug.

(*c*) An expiration date that is 12 months after the month during which the batch was certified.

(ii) On the label of the immediate container or other labeling attached to or within the package, adequate directions for lay use.

(3) *Requests for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The neomycin sulfate (commercial grade) used in making the batch for potency, toxicity, moisture, pH, and identity.

(*b*) The batch for potency.

(ii) Samples required:

(*a*) The neomycin sulfate (commercial grade) used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of five immediate containers.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(4) *Fees.* $4.00 for each immediate container or package in the samples submitted in accordance with subparagraph (3)(ii) of this paragraph.

(b) *Tests and methods of assay; potency.* Proceed as directed in § 148i.1(b)(1), except prepare the sample for assay as follows: Weigh accurately about 3 grams into a 15-milliliter centrifuge tube, cap the tube with aluminum foil, and heat over a steam bath until the cream is liquefied. Add an accurately measured volume of from 7 to 9 milliliters of a 10 percent solution of ammonia. Stir thoroughly to allow the heavy precipitate of aluminum hydroxide to form. Blend the contents for at least 3 minutes in a suitable homogenizer. Transfer the homogenized mixture into the centrifuge tube and centrifuge for 20 minutes at 3000 revolutions per minute. Remove 1.0 milliliter of the clear supernatant and evaporate to dryness under a stream of air. Dissolve and dilute the residue with 0.1*M* potassium phosphate buffer, pH 8.0, to the proper prescribed reference concentration of neomycin. The potency is satisfactory if it is not less than 90 percent and not more than 140 percent of the number of milligrams of neomycin that the product is represented to contain.

§ 148i.30a Neomycin sulfate (commercial grade)-aluminum chlorohydroxide deodorant lotion; neomycin sulfate (commercial grade)-aluminum chlorohydroxide-aluminum chloride deodorant lotion.

(a) *Requirements for certification—*(1) *Standards of identity, strength, quality, and purity.* Neomycin sulfate (commercial grade)-aluminum chlorohydroxide deodorant lotion contains neomycin sulfate (commercial grade) and aluminum chlorohydroxide in a suitable lotion vehicle. It contains, in each milliliter, the following:

(i) 1.75 milligrams of neomycin and 100 milligrams of aluminum chlorohydroxide (anhydrous); or

(ii) 3.5 milligrams of neomycin and either 142 milligrams or 152 milligrams of aluminum chlorohydroxide (anhydrous); or

(iii) 1 milligram of neomycin and 160 milligrams of aluminum chlorohydroxide (anhydrous).

Neomycin sulfate (commercial grade)-aluminum chlorohydroxide-aluminum chloride deodorant lotion contains, in each milliliter, 1.75 milligrams of neomycin, 176 milligrams of aluminum chlorohydroxide (anhydrous), and 10 milligrams of aluminum chloride. The preparations may also contain one or more suitable emollients, perfumes, colorings, dispersants, solubilizers, buffers, and preservatives in an aqueous vehicle. Their pH is not less than 3.5 and not more than 6.5. The neomycin sulfate (commercial grade) used conforms to the standards of § 148i.31(a)(1). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(i) On the label of the immediate container and on the outside wrapper or container, if any:

(*a*) The batch mark.

(*b*) The name and quantity of each active ingredient contained in the drug.

(*c*) An expiration date that is 12 months after the month during which the batch was certified.

(ii) On the label of the immediate container or other labeling attached on or within the package, adequate directions for lay use.

(3) *Requests for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The neomycin sulfate (commercial grade) used in making the batch for potency, toxicity, moisture, pH, and identity.

(*b*) The batch for potency and pH.

(ii) Samples required:

(*a*) The neomycin sulfate (commercial grade) used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of five immediate containers.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(4) *Fees.* $4.00 for each immediate container or package in the samples submitted in accordance with subparagraph (3)(ii) of this paragraph.

(b) *Tests and methods of assay—*(1) *Potency.* Proceed as directed in § 148i.1(b)(1), except prepare the sample for assay as follows: Remove a 3.0-milliliter portion with a suitable syringe and transfer to a 15-milliliter centrifuge tube. Add an accurately measured volume of from 7 to 9 milliliters of a 10 percent solution of ammonia. Stir thoroughly to allow the heavy precipitate of aluminum hydroxide to form. Blend the contents for at least 3 minutes in a suitable homogenizer. Transfer the homogenized mixture into the centrifuge tube and centrifuge for 20 minutes at 3000 revolutions per minute. Remove 1.0 milliliter of the clear supernatant and evaporate to dryness under a stream of air. Dissolve and dilute the residue with 0.1*M* potassium phosphate buffer, pH 8.0, to the proper prescribed reference concentration of neomycin. The potency is satisfactory if it is not less than 90 percent and not more than 140 percent of the number of milligrams of neomycin that the product is represented to contain.

(2) *pH.* Proceed as directed in § 141a.5(b) of this chapter, using the undiluted sample.

§ 148i.30b Neomycin sulfate-aluminum chlorohydroxide deodorant lotion.

Neomycin sulfate-aluminum chlorohydroxide deodorant lotion conforms to all requirements and is subject to all procedures prescribed by § 148i.30a for neomycin sulfate (commercial grade)-aluminum chlorohydroxide deodorant lotion, except that:

(a) Each milliliter contains 3.5 milligrams of neomycin and 160 milligrams of aluminum chlorohydroxide (anhydrous).

(b) The neomycin sulfate used conforms to the standards prescribed by § 148i.1(a)(1)(i), (v), (vi), and (vii).

§ 148i.36 Neomycin sulfate-polymyxin B sulfate-tyrothricin-benzocaine troches.

(a) *Requirements for certification—*(1) *Standards of identity, strength, quality, and purity.* Neomycin sulfate-polymyxin B sulfate-tyrothricin-benzocaine troches are troches composed of neomycin sulfate, polymyxin B sulfate, tyrothricin, and benzocaine with one or more suitable lubricants, binders, fillers, colorings, and flavorings. Each troche contains 3.5 milligrams of neomycin, 1,000 units of polymyxin B, 1.0 milligram of tyrothricin, and 10 milligrams of benzocaine. The moisture content is not more than 2.0 percent. The neomycin sulfate used conforms to the standards of § 148i.1(a)(1)(i), (iv), (v), (vi), and (vii). The polymyxin B sulfate used conforms to the standards prescribed by § 148p.1(a)(1)(i), (iv), (v), (vi), (vii), and (ix) of this chapter. The tyrothricin used conforms to the standards prescribed by § 148r.1(a)(1) of this chapter. Each other substance used, if its name

is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(i) On the label of the immediate container and on the outside wrapper or container, if any:

(*a*) The batch mark.

(*b*) The name and quantity of each active ingredient contained in the drug.

(*c*) An expiration date that is 12 months after the month during which the batch was certified.

(ii) On the label of the immediate container or other labeling attached to or within the package, adequate directions for lay use of the drug.

(3) *Requests for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The neomycin sulfate used in making the batch for potency, toxicity, moisture, pH, and identity.

(*b*) The polymyxin B sulfate used in making the batch for potency, toxicity, moisture, pH, residue on ignition, and identity.

(*c*) The tyrothricin used in making the batch for potency, moisture, and identity.

(*d*) The batch for neomycin content, polymyxin content, tyrothricin content, and moisture.

(ii) Samples required:

(*a*) The neomycin sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The polymyxin B sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*c*) The tyrothricin used in making the batch: 5 packages, each containing approximately 300 milligrams.

(*d*) The batch: A minimum of 30 troches.

(*e*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(4) *Fees.* $1.25 for each troche in the sample submitted in accordance with subparagraph (3) (ii) (*d*) of this paragraph; $4.00 for each package in the samples submitted in accordance with subparagraph (3) (ii) (*a*), (*b*), (*c*), and and (*e*) of this paragraph.

(b) *Tests and method of assay*—(1) *Potency*—(i) *Neomycin content.* Proceed as directed in § 148i.1(b) (1), except prepare the sample for assay as follows: Place a representative of troches in a high-speed glass blender and add sufficient 0.1*M* potassium phosphate buffer, pH 8.0, to give a stock solution of convenient concentration. Blend until the troches are completely disintegrated. Make proper estimated dilutions with 0.1*M* potassium phosphate buffer, pH 8.0, to the prescribed reference concentration. The content of neomycin is satisfactory if it is not less than 90 percent and not more than 125 percent of the number of milligrams of neomycin that it is represented to contain.

(ii) *Polymyxin content.* Proceed as directed in § 148p.1(b) (1) of this chapter, except:

(*a*) Prepare the sample for assay as follows: Dissolve a representative number of troches in sufficient 10 percent potassium phosphate buffer, pH 6.0, to give a stock solution of convenient concentration. Make proper estimated dilutions with 10 percent potassium phosphate buffer, pH 6.0, to the reference concentration of 10 units of polymyxin per milliliter.

(*b*) Add to each concentration of the polymyxin standard curve a quantity of neomycin to yield the same concentration of neomycin as that present when the sample is diluted to contain 10 units of polymyxin per milliliter. Also add to each concentration of the polymyxin standard curve a quantity of sucrose to yield the same concentration of sucrose as that present when the sample is diluted to contain 10 units of polymyxin per milliliter.

The content of polymyxin is satisfactory if it is not less than 90 percent and not more than 125 percent of the number of units of polymyxin that it is represented to contain.

(iii) *Tyrothricin content.* Proceed as directed in § 148r.1(b) (1) of this chapter, except prepare the sample for assay as follows: Dissolve a representative number of troches in sufficient 95 percent alcohol to give a concentration of convenient concentration. Make proper estimated dilutions with 95 percent alcohol to the prescribed reference concentration. The content of tyrothricin is satisfactory if it is not less than 90 percent and not more than 125 percent of the number of milligrams of tyrothricin that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter.

§ 148i.37 Neomycin sulfate-gramicidin-propyl *p*-aminobenzoate chewing troches.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Neomycin sulfate-gramicidin-propyl *p*-aminobenzoate chewing troches are troches composed of neomycin sulfate, gramicidin, and propyl *p*-aminobenzoate with one or more suitable binders, solvents, fillers, masticatory substances, flavorings, colorings, and preservatives. Each troche contains 3.5 milligrams of neomycin, 0.25 milligram of gramicidin, and 2.0 milligrams of propyl *p*-aminobenzoate. The neomycin sulfate used conforms to the standards prescribed by § 148i.1(a) (1) (i), (iv), (v), (vi), and (vii). The gramicidin used conforms to the standards prescribed by § 148f.1(a) (1) of this chapter. Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(i) On the label of the immediate container and on the outside wrapper or container, if any:

(*a*) The batch mark.

(*b*) The name and quantity of each active ingredient contained in the drug.

(*c*) An expiration date that is 12 months after the month during which the batch was certified.

(ii) On the label of the immediate container or other labeling attached to or within the package, adequate directions for lay use of the drug.

(3) *Requests for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The neomycin sulfate used in making the batch for potency, toxicity, moisture, pH, and identity.

(*b*) The gramicidin used in making the batch for potency, toxicity, moisture, residue on ignition, melting point, identity, and crystallinity.

(*c*) The batch for neomycin content and gramicidin content.

(ii) Samples required:

(*a*) The neomycin sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The gramicidin used in making the batch: 10 packages, each containing approximately 500 milligrams.

(*c*) The batch: A minimum of 30 troches.

(*d*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(4) *Fees.* $1.00 for each troche in the sample submitted in accordance with subparagraph (3) (ii) (*c*) of this paragraph; $4.00 for each package in the samples submitted in accordance with subparagraph (3) (ii) (*a*), (*b*), and (*d*) of this paragraph.

(b) *Tests and methods of assay; potency*—(1) *Neomycin content.* Proceed as directed in § 148i.1(b) (1) except prepare the sample for assay as follows: Place a representative number of troches in a high-speed glass blender and add sufficient 0.1*M* potassium phosphate buffer, pH 8.0, to give a stock solution of convenient concentration. Blend until the troches are completely disintegrated. Make proper estimated dilutions with 9.1*M* potassium phosphate buffer, pH 8.0, to the prescribed reference concentration. Its content of neomycin is satisfactory if it is not less than 90 percent and not more than 125 percent of the number of milligrams of neomycin that it is represented to contain.

(2) *Gramicidin content.* Proceed as directed in § 148f.1(b) (1) of this chapter, except prepare the sample for assay as follows: Place a representative number of troches in an Erlenmeyer flask and add 50 milliliters of 80 percent ethyl alcohol. Shake until the entire outer coating of the troches has been removed. Filter the solution through a cotton plug. Wash the contents of the flask with several portions of 80 percent ethyl alcohol and pass the washings through the cotton plug filter. Quantitatively transfer the combined filtrate to a 100-milliliter volumetric flask and adjust to volume with 80 percent ethyl alcohol. Make proper estimated dilutions with 95 percent ethyl alcohol to the reference concentration.

Its content of gramicidin is satisfactory if it is not less than 90 percent and not more than 125 percent of the number of milligrams of gramicidin that it is represented to contain.

§ 148i.38 Neomycin sulfate-gramicidin-benzocaine troches; neomycin sulfate-gramicidin-propyl *p*-aminobenzoate troches.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Neomycin sulfate-gramicidin-benzocaine troches or neomycin sulfate-gramicidin-propyl *p*-aminobenzoate troches are troches composed of neomycin sulfate, gramicidin, and benzocaine or propyl *p*-aminobenzoate, with or without one or more suitable fillers, lubricants, colorings, and flavorings. Each troche contains either:

(i) 2.5 milligrams of neomycin, 0.25 milligram of gramicidin, and 10 milligrams of benzocaine; or

(ii) 3.5 milligrams of neomycin, 0.25 milligram of gramicidin, and 2 milligrams of propyl *p*-aminobenzoate.

The moisture content is not more than 3.0 percent. The neomycin sulfate used conforms to the standards prescribed by § 148i.1(a)(1)(i), (iv), (v), (vi), and (vii). The gramicidin used conforms to the standards prescribed by § 148f.1(a)(1) of this chapter. Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(i) On the label of the immediate container and on the outside wrapper or container, if any:

(*a*) The batch mark.

(*b*) The name and quantity of each active ingredient contained in the drug.

(*c*) An expiration date that is 12 months after the month during which the batch was certified.

(ii) On the label of the immediate container or other labeling attached to or within the package, adequate directions for lay use of the drug.

(3) *Requests for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The neomycin sulfate used in making the batch for potency, toxicity, moisture, pH, and identity.

(*b*) The gramicidin used in making the batch for potency, toxicity, moisture, residue on ignition, melting point, identity, and crystallinity.

(*c*) The batch for neomycin content, gramicidin content, and moisture.

(ii) Samples required:

(*a*) The neomycin sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The gramicidin used in making the batch: 10 packages, each containing approximately 500 milligrams.

(*c*) The batch: A minimum of 30 troches.

(*d*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(4) *Fees.* $1.00 for each troche in the sample submitted in accordance with subparagraph (3)(ii)(*c*) of this paragraph; $4.00 for each package in the samples submitted in accordance with subparagraph (3)(ii) (*a*), (*b*), and (*d*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Neomycin content.* Proceed as directed in § 148i.1(b)(1), except prepare the sample for assay as follows: Place a representative number of troches in a high-speed glass blender, add a quantity of 0.1*M* potassium phosphate buffer, pH 8.0, to make a stock solution of convenient concentration and blend until troches are completely disintegrated. Make estimated dilutions to the reference concentration with 0.1*M* potassium phosphate buffer, pH 8.0. The content of neomycin is satisfactory if it is not less than 90 percent and not more than 125 percent of the number of milligrams of neomycin that it is represented to contain.

(ii) *Gramicidin content.* Proceed as directed in § 148f.1(b)(1) of this chapter, except prepare the sample for assay as follows: Place a representative number of troches in an Erlenmeyer flask and add a quantity of 95 percent ethyl alcohol that will give a stock solution of convenient concentration. Stopper the flask and shake on a mechanical shaker until the troches are completely disintegrated. Make proper estimated dilutions to the reference concentration with 95 percent ethyl alcohol. The content of gramicidin is satisfactory if it is not less than 90 percent and not more than 125 percent of the number of milligrams of gramicidin that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter.

§ 148i.40 Neomycin sulfate-polymyxin B sulfate-methoxamine hydrochloride nasal solution.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Neomycin sulfate-polymyxin B sulfate-methoxamine hydrochloride nasal solution is a solution containing, in each milliliter, 3.5 milligrams of neomycin, 5,000 units of polymyxin B, 5 milligrams of methoxamine hydrochloride, and one or more suitable buffers and preservatives. Its pH is not less than 4.2 and not more than 7.0. The neomycin sulfate used conforms to the standards prescribed by § 148i.1(a)(1)(i), (iv), (vi), and (vii). The polymyxin B sulfate used conforms to the standards prescribed by § 148p.1(a)(1)(i), (iv), (vi), (vii), and (ix) of this chapter. Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Requests for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assay on:

(*a*) The neomycin sulfate used in making the batch for potency, toxicity, pH, and identity.

(*b*) The polymycin B sulfate used in making the batch for potency toxicity, pH, residue on ignition, and identity.

(*c*) The batch for neomycin content, polymyxin content, and pH.

(ii) Samples required:

(*a*) The neomycin sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The polymyxin B sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*c*) The batch: A minimum of six immediate containers.

(*d*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(4) *Fees.* $5.00 for each immediate container in the sample submitted in accordance with subparagraph (3)(ii)(*c*) of this paragraph; $4.00 for each package in the samples submitted in accordance with subparagraph (3)(ii) (*a*), (*b*), and (*d*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Neomycin content.* Proceed as directed in § 148i.7(b)(1). Its content of neomycin is satisfactory if it contains not less than 90 percent and not more than 125 percent of the number of milligrams of neomycin that it is represented to contain.

(ii) *Polymyxin content.* Remove an accurately measured representative portion with a suitable syringe and dilute to a convenient concentration with 10 percent potassium phosphate buffer, pH 6.0. Further dilute to a concentration of 10 units of polymyxin per milliliter with 10 percent potassium phosphate buffer, pH 6.0. Proceed as directed in § 148p.1(b)(1) of this chapter, except:

(*a*) Add to each concentration of the polymyxin standard curve a quantity of neomycin to yield the same concentration of neomycin as that present when the sample is diluted to contain 10 units of polymyxin per milliliter.

(*b*) If the dosage form contains thimerosal as a preservative, adjust the agar for the seed layer by adding 300 milligrams of thioglycolic acid per liter.

Its content of polymyxin is satisfactory if it contains not less than 90 percent and not more than 125 percent of the number of units of polymyxin that it is represented to contain.

(2) *pH.* Proceed as directed in § 141a.5(b) of this chapter, using the undiluted sample.

§ 148i.41 Neomycin sulfate-polymyxin B sulfate-phenylephrine hydrochloride-thenyldiamine hydrochloride nasal solution.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Neomycin sulfate-polymyxin B sulfate-phenylephrine hydrochloride-thenyldiamine hydrochloride nasal solution is a solution containing, in each milliliter, 0.6 milligram of neomycin, 3,000 units of polymyxin B,

5 milligrams of phenylephrine hydrochloride, 0.5 milligram of thenyldiamine hydrochloride, and one or more suitable buffers and preservatives. Its pH is not less than 4.2 and not more than 7.0. The neomycin sulfate used conforms to the standards prescribed by § 148i.1(a)(1)(i), (iv), (vi), and (vii). The polymyxin B sulfate used conforms to the standards prescribed by § 148p.1(a)(1)(i), (iv), (vi), (vii), and (ix) of this chapter. Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Requests for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The neomycin sulfate used in making the batch for potency, toxicity, pH, and identity.

(*b*) The polymyxin B sulfate used in making the batch for potency, toxicity, pH, residue on ignition, and identity.

(*c*) The batch for neomycin content, polymyxin content, and pH.

(ii) Samples required:

(*a*) The neomycin sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The polymyxin B sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*c*) The batch: A minimum of 6 immediate containers.

(*d*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(4) *Fees.* $5.00 for each immediate container in the sample submitted in accordance with subparagraph (3)(ii)(*c*) of this paragraph; $4.00 for each package in the samples submitted in accordance with subparagraph (3)(ii)(*a*), and (*b*), and (*d*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Neomycin content.* Proceed as directed in § 148i.7(b)(1).

Its content of neomycin is satisfactory if it contains not less than 90 percent and not more than 125 percent of the number of milligrams of neomycin that it is represented to contain.

(ii) *Polymyxin content.* Remove an accurately measured representative portion with a suitable syringe and dilute to a convenient concentration with 10 percent potassium phosphate buffer, pH 6.0. Further dilute to a concentration of 10 units of polymyxin per milliliter with 10 percent potassium phosphate buffer, pH 6.0. Proceed as directed in § 148p.1(b)(1) of this chapter, except:

(*a*) Add to each concentration of the polymyxin standard curve a quantity of neomycin to yield the same concentration of neomycin as that present when the sample is diluted to contain 10 units of polymyxin per milliliter.

(*b*) If the dosage form contains thimerosal as a preservative, adjust the agar for the seed layer by adding 300 milligrams of thioglycolic acid per liter.

Its content of polymyxin is satisfactory if it contains not less than 90 percent and not more than 125 percent of the number of units of polymyxin that it is represented to contain.

(2) *pH.* Proceed as directed in § 141a.5(b) of this chapter, using the undiluted sample.

§ 148i.42 Neomycin sulfate-gramicidin-phenylephrine hydrochloride nasal solution.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Neomycin sulfate-gramicidin-phenylephrine hydrochloride nasal solution is a solution containing, in each milliliter, either 0.8 milligram of neomycin, 0.05 milligram of gramicidin, and 2.5 milligrams of phenylephrine hydrochloride, or 0.66 milligram of neomycin, 0.05 milligram of gramicidin, and 5.0 milligrams of phenylephrine hydrochloride. It may also contain one or more suitable preservatives, solvents, surfactants, and buffers. Its pH is not less than 4.5 and not more than 7.0. The neomycin sulfate used conforms to the standards prescribed by § 148i.1(a)(1)(i), (iv), (vi), and (vii). The gramicidin used conforms to the standards prescribed by § 148f.1(a)(1)(i), (ii), (iv), (v), and (vi) of this chapter. Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(i) On the label of the immediate container and on the outside wrapper or container, if any:

(*a*) The batch mark.

(*b*) The name and quantity of each active ingredient contained in the drug.

(*c*) An expiration date that is 12 months after the month during which the batch was certified.

(ii) On the label of the immediate container or other labeling attached to or within the package, adequate directions for lay use of the drug.

(3) *Requests for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The neomycin sulfate used in making the batch for potency, toxicity, pH, and identity.

(*b*) The gramicidin used in making the batch for potency, toxicity, residue on ignition, melting point, identity, and crystallinity.

(*c*) The batch for neomycin content, gramicidin content, and pH.

(ii) Samples required:

(*a*) The neomycin sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The gramicidin used in making the batch: 10 packages, each containing approximately 500 milligrams.

(*c*) The batch: A minimum of six immediate containers.

(*d*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(4) *Fees.* $5.00 for each immediate container in the sample submitted in accordance with subparagraph (3)(ii)(*c*) of this paragraph; $4.00 for each package in the samples submitted in accordance with subparagraph (3)(ii)(*a*), (*b*), and (*d*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Neomycin content.* Proceed as directed in § 148i.20(b)(1)(i). Its content of neomycin is satisfactory if it is not less than 90 percent and not more than 125 percent of the number of milligrams of neomycin that it is represented to contain.

(ii) *Gramicidin content.* Proceed as directed in § 148i.20(b)(1)(iii). Its content of gramicidin is satisfactory if it contains not less than 90 percent and not more than 125 percent of the number of milligrams of gramicidin that it is represented to contain.

(2) *pH.* Proceed as directed in § 141a.5(b) of this chapter, using the undiluted sample.

§ 148i.43 Neomycin sulfate-gramicidin-thonzylamine hydrochloride-thonzonium bromide-phenylephrine hydrochloride nasal solution.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Neomycin sulfate-gramicidin-thonzylamine hydrochloride-thonzonium bromide-phenylephrine hydrochloride nasal solution is a solution containing, in each milliliter, 0.66 milligram of neomycin, 0.05 milligram of gramicidin, 10.0 milligrams of thonzylamine hydrochloride, 0.05 milligram of thonzonium bromide, 2.5 milligrams of phenylephrine hydrochloride, and one or more suitable preservatives, solvents, surfactants, and buffers. Its pH is not less than 4.5 and not more than 7.0. The neomycin sulfate used conforms to the standards prescribed by § 148i.1(a)(1)(i), (iv), (vi), and (vii). The gramicidin used conforms to the standards of § 148f.1(a)(1)(i), (ii), (iv), (v), and (vi) of this chapter. Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(i) On the label of the immediate container and on the outside wrapper or container, if any:

(*a*) The batch mark.

(*b*) The name and quantity of each active ingredient contained in the drug.

(*c*) An expiration date that is 12 months after the month during which the batch was certified.

(ii) On the label of the immediate container or other labeling attached to or within the package, adequate directions for lay use of the drug.

(3) *Requests for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The neomycin sulfate used in making the batch for potency, toxicity, pH, and identity.

(*b*) The gramicidin used in making the batch for potency, toxicity, residue on ignition, melting point, identity, and crystallinity.

(*c*) The batch for neomycin content, gramicidin content, and pH.

(ii) Samples required:

(*a*) The neomycin sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The gramicidin used in making the batch: 10 packages, each containing approximately 500 milligrams.

(*c*) The batch: A minimum of six immediate containers.

(*d*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(4) *Fees.* $5.00 for each immediate container in the sample submitted in accordance with subparagraph (3) (ii) (*c*) of this paragraph; $4.00 for each package in the samples submitted in accordance with subparagraph (3) (ii) (*a*), (*b*), and (*d*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Neomycin content.* Proceed as directed in § 148i.20(b) (1) (i). Its content of neomycin is satisfactory if it is not less than 90 percent and not more than 125 percent of the number of milligrams of neomycin that it is represented to contain.

(ii) *Gramicidin content.* Proceed as directed in § 148i.20(b) (1) (iii). Its content of gramicidin is satisfactory if it contains not less than 90 percent and not more than 125 percent of the number of milligrams of gramicidin that it is represented to contain.

(2) *pH.* Proceed as directed in § 141a.5(b) of this chapter, using the undiluted sample.

§ 148m.2 Triacetyloleandomycin.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Triacetyloleandomycin is the triacetyl ester of oleandomycin base or a mixture of two or more such esters. It is a white crystalline powder. It is so purified that:

(i) Its potency is not less than 750 micrograms of triacetyloleandomycin per milligram.

(ii) It passes the toxicity test.

(iii) Its moisture content is not more than 1.0 percent.

(iv) Its pH in an aqueous alcohol solution containing 100 milligrams of triacetyloleandomycin per milliliter is not less than 7.0 and not more than 8.5.

(v) Its residue on ignition is not more than 0.1 percent.

(vi) It gives a positive identity test for oleandomycin.

(vii) Its R_f value by paper chromatograph is approximately 0.85. If more than one spot appears on the paper chromatogram, determine its acetyl value, which is not less than 15.3 percent and not more than 16.0 percent.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3(b) of this chapter. Its expiration date is 12 months.

(3) *Requests for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, toxicity, moisture, pH, residue on ignition, identity, R_f value, acetyl value (only if more than one spot is present in the determination of R_f value), and crystallinity.

(ii) Samples of the batch: 10 packages, each containing approximately equal portions of not less than 500 milligrams.

(4) *Fees.* $5.00 for each container in the sample submitted in accordance with subparagraph (3) (ii) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Use any one of the following methods; however, the results obtained from the method in subdivision (iii) shall be conclusive.

(i) *Chemical method*—(*a*) *Reagents and equipment.* (*1*) Methyl orange reagent: Shake 0.5*M* boric acid solution for 12 hours (to insure saturation) with an excess of methyl orange indicator. An alternative method is to heat the mixture to about 50° C. and shake for about an hour. Then allow to cool. Filter the saturated dye solution and wash three times with chloroform. Store the dye solution over chloroform.

(*2*) Acid-alcohol solution: Add 2 milliliters of concentrated sulfuric acid to 98 milliliters of absolute methyl alcohol.

(*3*) Glycerin: Reagent grade.

(*4*) Centrifuge tubes: 40 milliliters, glass-stoppered.

(*b*) *Procedure.* Prepare a standard solution in chloroform containing 50.0 milligrams of oleandomycin base in 200 milliliters. Transfer 10.0 milliliters of the solution to a 100-milliliter volumetric flask and dilute to volume with chloroform. Transfer 2.0, 4.0, 6.0, and 8.0 milliliters of this solution to glass-stoppered centrifuge tubes (40-milliliter size) and dilute to a total volume of 20.0 milliliters each with chloroform. To the 20 milliliters of the solution present in each 40-milliliter size centrifuge tube, add 0.2 milliliter of glacial acetic acid, 0.2 milliliter of glycerin, and 0.4 milliliter of methyl orange reagent. Shake for 5 minutes and centrifuge for 3 minutes. Immediately transfer to another tube a 10.0-milliliter aliquot from the chloroform (lower) layer. Care must be exercised to see that no portion of the dye-glycerin phase is included with the chloroform aliquot. Add 1.0 milliliter of acid-alcohol solution to this chloroform aliquot, mix well, and read the absorbancy at 535 mu using a 1-centimeter cell and a suitable photometer and using chloroform, similarly treated, as a blank. Prepare a standard curve, plotting the absorbance values of the standard solution against the concentration expressed in micrograms of oleandomycin base per aliquot. Accurately weigh the sample to be tested to give 50 milligrams (estimated) of oleandomycin base, dissolve in chloroform, and make to 200 milliliters with chloroform. Transfer 10.0 milliliters to a 100-milliliter volumetric flask and make to volume with chloroform. Transfer 5.0 milliliters to a glass-stoppered centrifuge tube and proceed as above. Determine the potency of the sample from the standard curve.

(ii) *Plate bioassay.* Proceed as directed in § 148m.1(b) (1), except:

(*a*) Add 2.0 milliliters of polysorbate 80 to each 100 milliliters of the agar used for the base and seed layers.

(*b*) In lieu of the directions in § 148m.1(b) (1) (iii), dissolve a suitable weighed quantity of the triacetyloleandomycin working standard in sufficient 80 percent isopropyl alcohol-water solution to give a concentration of 1,000 micrograms of triacetyloleandomycin per milliliter. Use the solution the day that it is prepared.

(*c*) In lieu of the directions in § 148m.1(b) (1) (iv), dissolve the sample in sufficient 80 percent isopropyl alcohol-water solution to give a convenient stock solution. Further dilute in 0.2*M* potassium phosphate buffer, pH 10.5, to give a final concentration of 15 micrograms of triacetyloleandomycin per milliliter (estimated).

(*d*) In lieu of the directions in § 148m.1(b) (1) (vi), use the agar described in subdivision (*a*) of this subdivision for both layers. Use the plates as soon after seeding as practical. If they are not to be used immediately after seeding, refrigerate the inoculated plates until ready for use.

(*e*) In lieu of the directions for preparing the standard curve in § 148m.1 (b) (1) (vii), prepare the standard curve by diluting the stock triacetyloleandomycin standard solution in 0.2*M* potassium phosphate buffer, pH 10.5, to give concentrations of 9.6, 12.0, 15.0, 18.8, and 23.4 micrograms of triacetyloleandomycin per milliliter. The 15.0 micrograms per milliliter concentration is the reference concentration.

(*f*) In lieu of the directions in § 148m.1(b) (1) (viii), incubate the plates at 37° C. overnight. The concentration of the sample and standard being tested is 15.0 micrograms of triacetyloleandomycin per milliliter.

(iii) *Turbidimetric bioassay*—(*a*) *Culture media.* Use ingredients that conform to the standards prescribed by the U.S.P. or N.F., if any.

(*1*) Make nutrient agar for carrying the test organism as follows:

Peptone	6.0 gm.
Pancreatic digest of casein	4.0 gm.
Yeast extract	1.5 gm.
Beef extract	1.5 gm.
Dextrose	1.0 gm.
Agar	15.0 gm.
Distilled water, q.s	1,000.0 ml.

pH 6.5–6.6 after sterilization.

(*2*) Make nutrient broth for preparing an inoculum of the test organism as follows:

Peptone	5.0 gm.
Yeast extract	1.5 gm.
Beef extract	1.5 gm.
Sodium chloride	3.5 gm.
Dextrose	1.0 gm.
Dipotassium phosphate	3.68 gm.
Potassium phosphate	1.32 gm.
Distilled water, q.s	1,000.0 ml.

pH 7.0 after sterilization.

In lieu of preparing the media from the individual ingredients specified in this subdivision, they may be made from a dehydrated mixture which, when reconstituted with distilled water, has the same composition as such media. Minor modifications of the individual ingredients specified in this subdivision are permissible, if the resulting media possess growth-promoting properties at least equal to the media described.

(b) *Preparation of the inoculated broth.* The test organism in *Klebsiella pneumoniae* (A.T.C.C. 10031), noncapsulated, which is maintained on slants of nutrient agar prepared as described in subdivision (a) (1) of this subdivision. Transfer stock culture of the test organism every week to fresh nutrient agar slants and incubate overnight at 37° C. Suspend the growth from a freshly incubated slant in sterilized U.S.P. saline T.S., and inoculate a large nutrient agar surface such as that provided by a Roux bottle containing 300 milliliters of the nutrient agar. Spread the suspension of organism evenly over the entire nutrient agar surface and incubate overnight at 37° C. Harvest the growth from the surface, using 50 milliliters of sterilized U.S.P. saline T.S. per Roux bottle. Adjust the volume of the suspension so that a 1 + 24 dilution will give 25 percent light transmission when measured with a suitable photoelectric colorimeter having a 580 mμ filter and a 13-millimeter test tube as an absorption cell. The resulting suspension may be used for 1 week when stored under refrigeration. Prepare the daily inoculated broth by adding 0.2 milliliter of the adjusted suspension to each 100 milliliters of nutrient broth prepared as described in subdivision (a) (2) of this subdivision.

(c) *Working standard.* Prepare the daily standard curve by diluting the stock triacetyloleandomycin working standard solution prepared as described in subdivision (ii) (b) of this subparagraph with 1 percent potassium phosphate buffer, pH 6.0, to the following final concentrations: 15.0, 19.5, 25.0, 32.0, and 41.2 micrograms of triacetyloleandomycin per milliliter. The 25.0 micrograms per milliliter concentration is the reference concentration. Add 1 milliliter of each final concentration to each of three tubes having an outside dimension of 16 millimeters by 125 millimeters.

(d) *Preparation of sample.* Dissolve the sample under test with an 80 percent isopropyl alcohol-water mixture to prepare a convenient stock solution. Further dilute the stock solution in 1 percent potassium phosphate buffer, pH 6.0, to the reference concentration of 25 micrograms of triacetyloleandomycin per milliliter (estimated). Add 1 milliliter of the sample reference concentration solution to each of three tubes having an outside dimension of 16 millimeters by 125 millimeters.

(e) *Procedure.* Add 9 milliliters of the inoculated broth prepared as described in subdivision (b) of this subdivision to each of the tubes containing the sample and standard solutions, and immediately incubate in a 37° C. water bath for 3–4 hours. After incubation, remove all tubes and add 0.5 milliliter of 12 percent formaldehyde to each tube. Using a suitable photoelectric colorimeter at the wavelength of 530 mu, set the instrument at zero absorption with clear, uninoculated broth prepared as described in subdivision (a) (2) of this subdivision. Determine the absorption value for each sample and standard tube.

(f) *Estimation of potency.* Plot the average absorption values for each final concentration of the standard on semilogarithmic paper with absorption on the arithmetic scale and concentrations on the logarithmic scale. Construct the straight line of best fit through the points, either by inspection or by means of the following equations:

$$L=\frac{3a+2b+c-e}{5},$$

$$H=\frac{3e+2d+c-a}{5},$$

where:

L = Calculated absorption value for the lowest concentration of the standard curve;

H = Calculated absorption value for the highest concentration of the standard curve;

a, b, c, d, e = Average absorption value for the 15.0, 19.5, 25.0, 32.0, and 41.2 micrograms per milliliter concentrations of the standard curve, respectively.

Plot values obtained for L and H and connect with a straight line. Average the absorption values for the sample and determine the average concentration of the sample solutions from the standard curve. Multiply the concentration by the appropriate dilution factor to determine the triacetyloleandomycin content of the sample.

(2) *Toxicity.* Proceed as directed in § 141d.305(b) of this chapter, except administer a test dose of 0.5 milliliter of a suspension containing 200 milligrams of triacetyloleandomycin per milliliter in U.S.P. saline T.S.

(3) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter.

(4) *pH.* Proceed as directed in § 141a.5(b) of this chapter using a saturated solution prepared by adding 100 milligrams of triacetyloleandomycin per milliliter of water-ethyl alcohol (1:1) diluent.

(5) *Residue on ignition.* Proceed as directed in § 141e.401(g) of this chapter.

(6) *Identity.* Dissolve about 10 milligrams in 5 milliliters of hydrochloric acid and heat the solution in a boiling water bath; a greenish yellow color is produced.

(7) *R_f value.*—(i) *Apparatus and reagents* (a) Chromatographic chamber (cylinder glass-stoppered museum jar 11.5 inches x 3.5 inches).

(b) Chromatographic paper (8 inches x 8 inches Whatman No. 1).

(c) 0.1*N* hydrochloric acid.

(d) Resolving solvent: Butyl acetate, benzene, nitromethane, pyridine (5:5:5:1 by volume).

(e) Spray reagent: 15 grams antimony trichloride per 100 milliliters of chloroform.

(ii) *Procedure.* Dissolve the sample in chloroform to give a solution containing 10 milligrams to 20 milligrams of oleandomycin base equivalent per milliliter. Prepare a sheet of chromatographic paper by drawing a line of origin parallel to and 1 inch from the edge of the paper. Wet the paper thoroughly with the 0.1*N* hydrochloric acid and blot it firmly between sheets of absorbent paper. Starting 2 inches in from the edge and at 1-inch intervals, apply 3 microliters to 5 microliters of the sample solutions to the starting line. Allow a few minutes for the paper to dry partially. While the paper is still damp, form a cylinder by bringing the outer edges together, allowing about 1-inch overlap, and secure with a paper clip. Stand the paper in the chromatographic chamber, which has been filled to a depth of ½ inch with the resolving solvent. After the solvent front rises to a height of 4 inches to 5 inches above the origin, remove the paper from the tank and hang it up to air dry. Spray the dried paper with the antimony trichloride reagent. Hang the paper in a 100°C. oven for 3 minutes. A purple spot becomes visible for triacetyloleandomycin at an R_f value of about 0.85. The approximate R_f values for diacetyloleandomycin, monoacetyloleandomycin, and oleandomycin are, respectively, 0.72, 0.27, and 0.13.

(8) *Acetyl determination*—(i) *Apparatus and reagents.* (a) One 3-necked Pyrex flask of approximately 45 milliliters capacity, pear-shaped with T-joints, agar inlet tube, glass-stoppered funnel, glass condenser, and bubble counter.

(b) 50-milliliter Pyrex Erlenmeyer flask.

(c) 10-milliliter buret, calibrated to 0.02 milliliter.

(d) Anhydrous methyl alcohol, reagent grade.

(e) 2*N* sodium hydroxide solution.

(f) Sulfuric acid solution prepared by adding 100 milliliters of concentrated H_2SO_4 to 200 milliliters of water.

(g) 1*N* barium chloride solution.

(h) Phenolphthalein solution (1 percent in ethyl alcohol).

(i) Water-pumped nitrogen.

(j) NaOH solution, 0.015*N*.

(ii) *Procedure.* Weigh accurately (to 0.01 milligram) approximately 30 milligrams of the sample into the three-necked acetyl flask. Add 2.0 milliliters of methyl alcohol to dissolve the sample, then add slowly with gentle swirling, 1.0 milliliter of NaOH solution. Connect the gas inlet tube with bubble counter attached, and adjust nitrogen flow to about two bubbles a second. Put glass-stoppered funnel in centerneck of acetyl flask, and put about 5 milliliters of H_2O in the funnel. Add a boiling chip to the solution and attach condenser in the refluxing position with water cooling. Adjust burner flame under acetyl flask to reflux solution gently. Reflux for 30 minutes. Cool assembly slightly, then rinse down condenser (still in reflux position) with a few milliliters of H_2O. Reassemble condenser to the distillation position and add water through the funnel to make a total of approximately 5 milliliters of H_2O added to acetyl flask.

Adjust burner flame so that about 5 milliliters of H_2O and methyl alcohol is distilled over in approximately 10 minutes. Discard this distillate. Cool acetyl flask slightly. Acidify solution in flask by adding 1 milliliter of the sulfuric acid solution through the funnel. Adjust burner flame and distill over approximately 20 milliliters of distillate into an Erlenmeyer flask in about 20 minutes, adding water through the funnel as necessary. It is important to keep the liquid volume in the acetyl flask around 2 milliliters to 3 milliliters in order to obtain a quantitative recovery of the acetic acid. Collect a second fraction of distillate, about 10 milliliters in volume. As the second fraction is distilling, process the first fraction. Heat the first fraction and boil gently about 20 seconds. Add a few drops of $BaCl_2$ solution to check if any sulfate was distilled over. If the sulfate is present, discard and repeat the whole determination. If the sulfate is absent, immediately titrate the solution with the 0.015*N* NaOH solution to a faint-pink endpoint, using one drop of phenolphthalein solution as the indicator. Repeat the above procedure with the second fraction. If the second fraction requires less than 0.10 milliliter of the 0.015*N* NaOH solution and all the acetic acid has been distilled over, the determination is completed. If greater than this, collect a third fraction of approximately 10 milliliters and titrate this as before. Total volumes of NaOH used and calculate results as follows:

$$\frac{\text{Milliliters of NaOH} \times N\text{NaOH} \times 0.043 \times 100}{\text{Weight sample in grams}} = \text{Percent acetyl.}$$

(9) *Crystallinity.* Proceed as directed in § 141a.5(c) of this chapter.

§ 148m.4 Triacetyloleandomycin capsules; triacetyloleandomycin-_____ capsules (the blank being filled in with the established names of the other active ingredients present in accordance with paragraph (a)(1) of this section).

(a) *Requirements for certification—*(1) *Standards of identity, strength, quality, and purity.* Triacetyloleandomycin capsules are capsules composed of triacetyloleandomycin and one or more suitable buffers, diluents, binders, lubricants, and colorings. Each capsule contains 125 milligrams or 250 milligrams of triacetyloleandomycin. The following other drugs may be combined with triacetyloleandomycin, in the indicated amounts, per capsule: 121 milligrams _____ of triacetyloleandomycin, 120 milligrams of acetophenetidin, 30 milligrams of caffeine, and 150 milligrams of buclizine hydrochloride.

The moisture content is not more than 5.0 percent. The triacetyloleandomycin used conforms to the standards prescribed by § 148m.2(a)(1). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The triacetyloleandomycin used in making the batch for potency, toxicity, pH, residue on ignition, identity, R_f value, acetyl value (only if more than one spot is present in the determination of R_f value), and crystallinity.

(*b*) The batch for potency and moisture.

(ii) Simples required:

(*a*) Triacetyloleandomycin used in making the batch: 10 packages, each containing approximately 500 milligrams.

(*b*) The batch: A minimum of 30 capsules.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(4) *Fees.* $0.75 for each capsule in the sample submitted in accordance with subparagraph (3)(ii)(*b*) of this paragraph; $4.00 for each immediate container submitted in accordance with subparagraph (3)(ii)(*c*) of this paragraph; $5.00 for each immediate container submitted in accordance with subparagraph (3)(ii)(*a*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148m.2(b)(1)(ii) or (iii), except prepare the sample as follows: Place a representative number of capsules in a glass blending jar and add 500 milliliters of 80 percent isopropyl alcohol. Blend for 3 minutes with a high-speed blender; remove an aliquot and make the proper estimated dilutions to the prescribed reference concentration in 0.2*M* potassium phosphate buffer, pH 10.5, if the plate assay method is used, or in 1 percent potassium phosphate buffer, pH 6.0, if the turbidimetric assay is used. Its triacetyloleandomycin content is satisfactory if it contains not less than 90 percent nor more than 120 percent of the number of milligrams of triacetyloleandomycin that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter.

§ 148m.5 Triacetyloleandomycin-sulfadiazine-sulfamerazine-sulfamethazine tablets.

(a) *Requirements for certification—*(1) *Standards of identity, strength, quality, and purity.* Triacetyloleandomycin-sulfadiazine-sulfamerazine-sulfamethazine tablets are tablets composed of triacetyloleandomycin, sulfadiazine, sulfamerazine, and sulfamethazine, with one or more suitable buffers, diluents, binders, lubricants, colorings, and flavorings. Each tablet contains 75 milligrams of triacetyloleandomycin, 111 milligrams of sulfadiazine, 111 milligrams of sulfamerazine, and 111 milligrams of sulfamethazine. The moisture content is not more than 5 percent. The tablets shall disintegrate within 1 hour. The triacetyloleandomycin used conforms to the standards prescribed by § 148m.2(a)(1). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Requests for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The triacetyloleandomycin used in making the batch for potency, toxicity, pH, residue on ignition, identity, R_f value, acetyl value (only if more than one spot is present in the determination of R_f value), and crystallinity.

(*b*) The batch for potency, moisture, and disintegration time.

(ii) Samples required:

(*a*) Triacetyloleandomycin used in making the batch: 10 packages each containing approximately 500 milligrams.

(*b*) The batch:

(*1*) For all tests except disintegration time: A minimum of 30 tablets.

(2) For disintegration time: Six tablets.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(4) *Fees.* $0.75 for each tablet in the sample submitted in accordance with subparagraph (3)(ii)(*b*)(*1*) of this paragraph; $3.00 for all tablets in the sample submitted in accordance with subparagraph (3)(ii)(*b*)(2) of this paragraph; $4.00 for each immediate container submitted in accordance with subparagraph (3)(ii)(*c*) of this paragraph; $5.00 for each immediate container submitted in accordance with subparagraph (3)(ii)(*a*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148m.2(b)(1)(ii) or (iii), except prepare the sample as follows: Place a representative number of tablets in a glass blending jar and add 500 milliliters of 80 percent isopropyl alcohol. Blend for 3 minutes with a high-speed blender; remove an aliquot and make the proper estimated dilutions to the prescribed reference concentration in 0.2*M* potassium phosphate buffer, pH 10.5, if the plate assay is used, or in 1 percent potassium phosphate buffer, pH 6.0, if the turbidimetric assay is used. Its triacetyloleandomycin content is satisfactory if it contains not less than 90 percent nor more than 120 percent of the number of milligrams of triacetyloleandomycin that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter.

(3) *Disintegration time.* Proceed as directed in § 141a.9(c) of this chapter.

§ 148m.6 Triacetyloleandomycin-phenylpropanolamine hydrochloride-pheniramine maleate-pyrilamine maleate-calcium acetylsalicylate carbamide tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Triacetyloleandomycin-phenylpropanolamine hydrochloride - pheniramine maleate - pyrilamine maleate-calcium acetylsalicylate carbamide tablets are tablets composed of triacetyloleandomycin, phenylpropanolamine hydrochloride, pheniramine maleate, pyrilamine maleate, and calcium acetylsalicylate carbamide, with one or more suitable buffers, diluents, binders, lubricants, colorings, and flavorings. Each tablet contains 125 milligrams of triacetyloleandomycin, 12.5 milligrams of phenylpropanolamine hydrochloride, 6.25 milligrams of pheniramine maleate, 6.25 milligrams of pyrilamine maleate, and 382 milligrams of calcium acetylsalicylate carbamide. The moisture content is not more than 5 percent. The tablets shall disintegrate within 1 hour. The triacetyloleandomycin used conforms to the standards prescribed by § 148m.2(a)(1). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Requests for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The triacetyloleandomycin used in making the batch for potency, toxicity, pH, residue on ignition, identity, R_f value, acetyl value (only if more than one spot is present in the determination of R_f value), and crystallinity.

(*b*) The batch for potency, moisture, and disintegration time.

(ii) Samples required:

(*a*) Triacetyloleandomycin used in making the batch: 10 packages, each containing approximately 500 milligrams.

(*b*) The batch:

(*1*) For all tests except disintegration time: A minimum of 30 tablets.

(*2*) For disintegration time: Six tablets.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(4) *Fees.* $0.75 for each tablet in the sample submitted in accordance with subparagraph (3)(ii)(*b*)(*1*) of this paragraph; $3.00 for all tablets in the sample submitted in accordance with subparagraph (3)(ii)(*b*)(2) of this paragraph; $4.00 for each immediate container submitted in accordance with subparagraph (3)(ii)(*c*) of this paragraph; $5.00 for each immediate container submitted in accordance with subparagraph (3)(ii)(*a*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148m.2(b)(1)(ii) or (iii), except prepare the sample as follows: Place a representative number of tablets in a glass blending jar and add 500 milliliters of 80 percent isopropyl alcohol. Blend for 3 minutes with a high-speed blender; remove an aliquot and make the proper estimated dilutions to the prescribed reference concentration in 0.2*M* potassium phosphate buffer, pH 10.5, if the plate assay is used, or in 1 percent potassium phosphate buffer, pH 6.0, if the turbidimetric assay is used. Its triacetyloleandomycin content is satisfactory if it contains not less than 90 percent nor more than 120 percent of the number of milligrams of triacetyloleandomycin that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter.

(3) *Disintegration time.* Proceed as directed in § 141a.9(c) of this chapter.

§ 148m.7 Triacetyloleandomycin oral suspension; triacetyloleandomycin-_____ oral suspension (the blank being filled in with the established names of the other active ingredients present in accordance with paragraph (a)(1) of this section).

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Triacetyloleandomycin oral suspension is triacetyloleandomycin and one or more suitable buffers, dispersants, flavorings, colorings, and preservatives, suspended in a suitable and harmless vehicle. Each milliliter contains 25 milligrams of triacetyloleandomycin. The following other drugs may be combined with triacetyloleandomycin oral suspension in the indicated amounts per milliliter:

(i) 33 milligrams of sulfadiazine, 33 milligrams of sulfamerazine, and 33 milligrams of sulfamethazine; or

(ii) 2.5 milligrams of phenylpropanolamine hydrochloride, 1.25 milligrams of pheniramine maleate, 1.25 milligrams of pyrilamine maleate, 30 milligrams of acetaminophen.

Its pH is not less than 5.0 and not more than 8.0. The triacetyloleandomycin used conforms to the standards prescribed by § 148m.2(a)(1). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Requests for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The triacetyloleandomycin used in making the batch for potency, toxicity, moisture, pH, residue on ignition, identity, R_f value, acetyl value (only if more than one spot is present in the determination of R_f value), and crystallinity.

(*b*) The batch for potency and pH.

(iii) Samples required:

(*a*) Triacetyloleandomycin used in making the batch: 10 packages each containing approximately 500 milligrams.

(*b*) The batch: A minimum of five immediate containers.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(4) *Fees.* $4.00 for each immediate container in the samples submitted in accordance with subparagraph (3)(ii)(*b*) and (*c*) of this paragraph; $5.00 for each immediate container in the sample submitted in accordance with subparagraph (3)(ii)(*a*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceeds as directed in § 148m.2(b)(1)(ii) or (iii), except prepare the sample as follows: Transfer an appropriate sample (usually from 1.0 milliliter to 5.0 milliliters) to a 100-milliliter volumetric flask and dilute to mark with 80 percent isopropyl alcohol-water solution. Further dilute an aliquot of this solution to the prescribed reference concentration in 0.2*M* potassium phosphate buffer, pH 10.5, if the plate assay is used, or in 1 percent potassium phosphate buffer, pH 6.0, if the turbidimetric assay is used. Its triacetyloleandomycin content is satisfactory if it contains not less than 90 percent nor more than 120 percent of the number of milligrams of triacetyloleandomycin that it is represented to contain.

(2) *pH.* Proceed as directed in § 141a.5(b) of this chapter, using the undilted sample.

§ 148m.8 Triacetyloleandomycin for oral suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Triacetyloleandomycin for oral suspension is triacetyloleandomycin with suitable buffers, dispersants, preservatives, colorings, and flavorings. When the suspension is prepared as directed in its labeling, each milliliter contains 25 milligrams of triacetyloleandomycin, except if it is for pediatric use each milliliter contains 100 milligrams of triacetyloleandomycin. Its moisture content is not more than 2 percent. The pH of the suspension, when prepared as directed in its labeling, is not less than 5.0 and not more than 7.0. The triacetyloleandomycin used conforms to the standards prescribed by § 148m.2(a)(1). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Requests for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The triacetyloleandomycin used in making the batch for potency, toxicity, moisture, pH, residue on ignition, identity, R_f value, acetyl value (only if more than one spot is present in the determination of R_f value), and crystallinity.

(*b*) The batch for potency, moisture, and pH.

(ii) Samples required:

(*a*) Triacetyloleandomycin used in making the batch: 10 packages, each containing approximately 500 milligrams.

(*b*) The batch: A minimum of five immediate containers.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One package or each containing approximately 5 grams.

(4) *Fees.* $4.00 for each immediate container in the samples submitted in accordance with subparagraph (3) (ii) (*b*) and (*c*) of this paragraph; $5.00 for each immediate container in the sample submitted in accordance with subparagraph (3) (ii) (*a*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148m.2 (b) (1) (ii) or (iii), except prepare the sample as follows: Reconstitute the drug as directed in the labeling. Transfer an appropriate sample (usually 1.0 milliliter) to a 100-milliliater volumetric flask and dilute to mark with 80 percent isopropyl alcohol–water solution. Further dilute an aliquot of this solution to the prescribed reference concentration in 0.2*M* potassium phosphate buffer, pH 10.5, if the plate assay is used, or in 1 percent potassium phosphate buffer, pH 6.0, if the turbidimetric assay is used. Its triacetyloleandomycin content is satisfactory if it contains not less than 90 percent nor more than 120 percent of the number of milligrams of triacetyloleandomycin that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter.

(3) *pH.* Proceed as directed in § 141a.5(b) of this chapter, except use the suspension obtained after constituting the drug as directed in its labeling.

§ 148n.25 Oxytetracycline hydrochloride–hydrocortisone aerosol topical.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Oxytetracycline hydrochloride-hydrocortisone areosol topical is oxytetracycline hyrochloride and hydrocortisone in a suitable ointment base, packaged with one or more suitable inert gasgases. Each spray pack contains 300 milligrams of oxytetracycline and 100 milligrams of hydrocortisone. The moisture content is not more than 1.0 percent. The oxytetracycline hydrochloride used conforms to the standards prescribed by § 148n.2(a) (1) (i), (vi), (vii), (viii), and (ix). Each other ingredient used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Requests for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The oxytetracycline hydrochloride used in making the batch for potency, moisture, pH, absorptivity, identity, and crystallinity.

(*b*) The batch for potency and moisture.

(ii) Samples required:

(*a*) The oxytetracycline hydrochloride used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of five immediate containers.

(*c*) In case of an initial request for certification each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(4) *Fees.* $4.00 for each immediate container or package in the samples submitted in accordance with subparagraph (3) (ii) (*a*), (*b*), and (*c*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148n.1 (b) (1) (i) or (ii), except prepare the sample for assay as follows: Remove the cap and plastic spray tip from the aerosol can. Attach a 10-inch length of suitable plastic tubing over the nozzle of the aerosol can. Shake the can gently two or three times, place the free end of the tubing into a 400-milliliter beaker, hold the can in an upright position and depress the nozzle. Empty the entire contents into the beaker. Carefully evaporate any residual propellant by heating the beaker over a steam bath. Rinse the tubing with a minimum amount of ethyl alcohol and add it to the contents in the beaker. Transfer the contents of the beaker with three 10-milliliter portions of ethyl alcohol to a 1-liter volumetric flask. Bring to volume with 0.1*N* hydrochloric acid and mix well. Filter 40 to 50 milliliters of this stock solution through a double thickness of filter paper, discarding the first 20 milliliters of filtrate. Remove an appropriate aliquot of the remaining filtrate and, using 0.1*M* potassium phosphate buffer, pH 4.5, make proper estimated dilutions to the prescribed reference concentration. Its content of oxytetracycline is satisfactory if it contains not less than 90 percent and not more than 120 percent of the number of milligrams of oxytetracycline that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141b.117(c) of this chapter.

§ 148n.26 Oxytetracycline hydrochloride-polymyxin B sulfate-hydrocortisone aerosol topical.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Oxytetracycline hydrochloride-polymyxin B sulfate-hydrocortisone aerosol topical is oxytetarcycline hydrochloride, polymyxin B sulfate, and hydrocortisone in a suitable ointment base, packaged with one or more suitable inert gases. Each spray pack contains 300 milligrams of oxytetracyline, 100,000 units of polymyxin B, and 100 milligrams of hydrocortisone. The moisture content is not more than 1.0 percent. The oxytetracycline hydrochloride used conforms to the standards prescribed by § 148n.2 (a) (1) (i), (vi), (vii), (viii), and (ix). The polymyxin B sulfate used conforms to the standards prescribed by § 148p.1 (a) (1) (i), (v), (vi), (vii), and (ix) of this chapter. Each other ingredient used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Requests for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The oxytetracycline hydrochloride used in making the batch for potency, moisture, pH, absorptivity, crystallinity, and identity.

(*b*) The polymyxin B sulfate used in making the batch for potency, moisture, pH, residue on ignition, and identity.

(*c*) The batch for oxytetracycline content, polymyxin content, and moisture.

(ii) Samples required:

(*a*) The oxytetracycline hydrochloride used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The polymyxin B sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*c*) The batch: A minimum of six immediate containers.

(*d*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(4) *Fees.* $5.00 for each immediate container in the sample submitted in accordance with subparagraph (3) (ii) (*c*) of this paragraph; $4.00 for each package in the samples submitted in accordance with subparagraph (3) (ii) (*a*), (*b*), and (*d*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Oxytetracycline content.* Proceed as directed in § 148n.25(b) (1) of this chapter. The content of oxytetracycline is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of oxytetracycline that it is represented to contain.

(ii) *Polymyxin content.* Remove the cap and plastic spray tip from the aerosol can. Attach a 10-inch length of suitable plastic tubing over the nozzle and shake the can gently. Place the free end of the tubing into a beaker of suitable size, hold the can upright, and depress the nozzle until the contents are completely emptied into the beaker. Carefully evaporate any residual propellant by heating the beaker over a steam bath. Proceed as directed in § 148n.20(b) (1) (ii) (*a*) or (*b*), except in lieu of weighing 1 gram of the sample, use the entire contents obtained. The content of polymyxin is satisfactory if it contains not less than 90 percent and not more than 135 percent of the number of units of polymyxin that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141b.117(c) of this chapter.

§ 148n.27 Oxytetracycline hydrochloride-polymyxin B sulfate topical powder.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Oxytetracycline hydro-

chloride-polymyxin B sulfate topical powder is oxytetracycline hydrochloride and polymyxin B sulfate with a suitable filler. Each gram contains 30 milligrams of oxytetracycline and 10,000 units of polymyxin B. The moisture content is not more than 2.0 percent. The oxytetracycline hydrochloride used conforms to the standards prescribed by § 148n.2 (a) (1) (i), (vi), (vii), (viii), and (ix). The polymyxin B sulfate used conforms to the standards prescribed by § 148p.1 (a) (1) (i), (v), (vi), (vii), and (ix) of this chapter. Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(i) On the label of the immediate container and on the outside wrapper or container, if any:

(*a*) The batch mark.

(*b*) The name and quantity of each active ingredient contained in the drug.

(*c*) An expiration date that is 12 months after the month during which the batch was certified.

(ii) On the label of the immediate container or other labeling attached to or within the package, adequate directions for lay use of the drug.

(3) *Requests for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The oxytetracycline hydrochloride used in making the batch for potency, moisture, pH, absorptivity, crystallinity, and identity.

(*b*) The polymyxin B sulfate used in making the batch for potency, moisture, pH, residue on ignition, and identity.

(*c*) The batch for oxytetracycline content, polymyxin content, and moisture.

(ii) Samples required:

(*a*) The oxytetracycline hydrochloride used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The polymyxin B sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*c*) The batch: A minimum of six immediate containers.

(*d*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(4) *Fees.* $5.00 for each immediate container in the sample submitted in accordance with subparagraph (3) (ii) (*c*) of this paragraph; $4.00 for each package in the samples submitted in accordance with subparagraph (3) (ii) (*a*), (*b*), and (*d*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Oxytetracycline content.* Proceed as directed in § 148n.1(b) (1) (i) or (ii), except prepare the sample for assay as follows: Place an accurately weighed representative portion in a 1-liter volumetric flask, dissolve, and dilute to volume with 0.1*N* hydrochloric acid. Make the proper estimated dilutions of an aliquot of the stock solution to the prescribed reference concentration in 0.1*M* potassium phosphate buffer, pH 4.5. The content of oxytetracycline is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of oxytetracycline that it is represented to contain.

(ii) *Polymyxin content.* Proceed as directed in § 148p.1(b) (1) of this chapter, except prepare the sample for assay by either of the following methods:

(*a*) Accurately weigh approximately 1 gram of the powder and place in a 50-milliliter centrifuge tube. Add 15 milliliters of butyl alcohol and 1 drop of concentrated hydrochloric acid. Stir well. Add 20 milliliters of butyl alcohol and centrifuge for 10 minutes at 3,000 revolutions per minute. Decant the supernatant liquid and add 15 milliliters of acetone and 1 drop of concentrate hydrochloric acid to the residue. Stir well. Add 20 milliliters of acetone and centrifuge for 10 minutes at 3,000 revolutions per minute. Decant the supernatant liquid and repeat the acetone-acid extraction once more. Dissolve and dilute the residue with sufficient 10 percent potassium phosphate buffer, pH 6.0, to give a stock solution of convenient concentration. Remove an aliquot and make proper estimated dilutions to the prescribed reference concentration with 10 percent potassium phosphate buffer, pH 6.0.

(*b*) Place the accurately weighed sample in a filter funnel with a solvent-resistant membrane filter of 1.5μ porosity. Wash the powder with five 20-milliliter portions of acetone or until yellow color has disappeared. Remove the filter and soak in an adequate volume of 10 percent potassium phosphate buffer, pH 6.0. Quantitatively transfer to a 100-milliliter volumetric flask and adjust to volume with 10 percent potassium phosphate buffer, pH 6.0. Make proper estimated dilutions with 10 percent potassium phosphate buffer, pH 6.0, to the prescribed reference concentration.

The content of polymyxin is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of units of polymyxin that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter.

§ 148n.28 Oxytetracycline hydrochloride-polymyxin B sulfate-benzocaine for otic solution.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Oxytetracycline hydrochloride-polymyxin B sulfate-benzocaine for otic solution is a dry powder of oxytetracycline hydrochloride and polymyxin B sulfate, packaged in combination with a suitable diluting solution which contains benzocaine and a preservative. When prepared as directed in the labeling, each milliliter contains 5.0 milligrams of oxytetracycline, 10,000 units of polymyxin B, and 50 milligrams of benzocaine. The moisture content of the powder is not more than 3.0 percent. The oxytetracycline hydrochloride used conforms to the standards prescribed by § 148n.2(a) (1) (i), (vi), (vii), (viii), and (ix). The polymyxin B sulfate used conforms to the standards prescribed by § 148p.1(a) (1) (i), (v), (vi), (vii), and (ix) of this chapter. Each other ingredient used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Requests for certification; samples.* In addition to the requirements of § 148.4 of the chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The oxytetracycline hydrochloride used in making the batch for potency, moisture, pH, absorptivity, crystallinity, and identity.

(*b*) The polymyxin B sulfate used in making the batch for potency, moisture, pH, residue on ignition, and identity.

(*c*) The batch for oxytetracycline content, polymyxin content, and moisture content of the powder.

(ii) Samples required:

(*a*) The oxytetracycline hydrochloride used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The polymyxin B sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*c*) The batch: A minimum of seven immediate containers.

(*d*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(4) *Fees.* $5.00 for each immediate container in the sample submitted in accordance with subparagraph (3) (ii) (*c*) of this paragraph; $4.00 for each package in the samples submitted in accordance with subparagraph (3) (ii) (*a*), (*b*), and (*d*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Oxytetracycline content.* Proceed as directed in § 148n.1(b) (1) (i) or (ii), except prepare the sample for assay as follows: Reconstitute as directed in the labeling. Dilute 5.0 milliliters of this reconstituted sample to a volume of 100 milliliters with 0.1*N* hydrochloric acid. Make proper estimated dilutions to the prescribed reference concentration with 0.1*M* potassium phosphate buffer, pH 4.5. The content of oxytetracycline is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of oxytetracycline that it is represented to contain.

(ii) *Polymyxin content.* Proceed as directed in § 148n.27(b) (1) (ii) (*a*) or (*b*), except use the entire contents of the powder from each vial tested. Reconstitute a separate vial as directed in the labeling, measure the total volume that can be withdrawn, and, from the polymyxin content of the powder, calculate the number of units per milliliter. The content of polymyxin is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of units of polymyxin that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter.

§ 148n.29 Oxytetracycline hydrochloride-polymyxin B sulfate vaginal tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Oxytetracycline hydrochloride-polymyxin B sulfate vaginal tablets are tablets composed of oxytetracycline hydrochloride and polymyxin B sulfate, with one or more suitable diluents, binders, lubricants, and preservatives. Each tablet contains 100 milligrams of oxytetracycline and 100,000 units of polymyxin B. The moisture content is not more than 3.0 percent. The oxytetracycline hydrochloride used conforms to the standards prescribed by § 148n.2(a)(1) (i), (vi), (vii), (viii), and (ix). The polymyxin B sulfate used conforms to the standards prescribed by § 148p.1(a)(1) (i), (v), (vi), (vii), and (ix) of this chapter. Each other ingredient used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Requests for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The oxytetracycline hydrochloride used in making the batch for potency, moisture, pH, absorptivity, crystallinity, and identity.

(*b*) The polymyxin B sulfate used in making the batch for potency, moisture, pH, residue on ignition, and identity.

(*c*) The batch for oxytetracycline content, polymyxin content, and moisture.

(ii) Samples required:

(*a*) The oxytetracycline hydrochloride used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The polymyxin B sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*c*) The batch: A minimum of 30 tablets.

(*d*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(4) *Fees.* $1.00 for each tablet in the sample submitted in accordance with subparagraph (3)(ii)(*c*) of this paragraph; $4.00 for each package in the samples submitted in accordance with subparagraph (3)(ii) (*a*), (*b*), and (*d*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Oxytetracycline content.* Proceed as directed in § 148n.1(b)(1)(i) or (ii), except prepare the sample as follows: Place a representative number of tablets in a glass blending jar and blend 3 to 5 minutes with an appropriate volume of 0.1*N* hydrochloric acid to give a stock solution of convenient concentration. Its content of oxytetracycline is satisfactory if it contains not less than 90 percent and not more than 120 percent of the number of milligrams of oxytetracycline that it is represented to contain.

(ii) *Polymyxin content.* Proceed as directed in § 148n.27(b)(1)(ii) (*a*) or (*b*), using the finely powdered material from a representative number of tablets. Its content of polymyxin is satisfactory if it contains not less than 90 percent and not more than 120 percent of the number of units of polymyxin that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter.

§ 148p.7 Polymyxin B sulfate-gramicidin-hydroxyamphetamine hydrobromide-methapyrilene hydrochloride nasal solution.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Polymyxin B sulfate-gramicidin-hydroxyamphetamine hydrobromide-methapyrilene hydrochloride nasal solution is a solution containing, in each milliliter, 500 units of polymyxin B, 0.05 milligram of gramicidin, 10.0 milligrams of hydroxyamphetamine hydrobromide, and 2.0 milligrams of methapyrilene hydrochloride. It contains one or more suitable solvents, surfactants, buffers, colorings, and preservatives. Its pH is not less than 5.0 and not more than 6.0. The polymyxin B sulfate used conforms to the standards of § 148p.1(a)(1) (i), (iv), (vi), (vii), and (ix). The gramicidin used conforms to the standards of § 148f.1(a)(1) (i), (ii), (iv), (v), and (vi) of this chapter. Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(i) On the label of the immediate container and on the outside wrapper or container, if any:

(*a*) The batch mark.

(*b*) The name and quantity of each active ingredient contained in the drug.

(*c*) An expiration date that is 12 months after the month during which the batch was certified.

(ii) On the label of the immediate container or other labeling attached to or within the package, adequate directions for lay use of the drug.

(3) *Requests for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The polymyxin B sulfate used in making the batch for potency, toxicity, pH, residue on ignition, and identity.

(*b*) The gramicidin used in making the batch for potency, toxicity, residue on ignition, melting point, identity, and crystallinity.

(*c*) The batch for: Polymyxin content, gramicidin content, and pH.

(ii) Samples required:

(*a*) The polymyxin B sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The gramicidin used in making the batch: 10 packages, each containing approximately 500 milligrams.

(*c*) The batch: A minimum of six immediate containers.

(*d*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(4) *Fees.* $5.00 for each immediate container in the sample submitted in accordance with subparagraph (3)(ii) (*c*) of this paragraph; $4.00 for each package submitted in accordance with subparagraph (3)(ii) (*a*), (*b*), and (*d*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Polymyxin content.* Remove an accurately measured representative portion and dilute with 10 percent potassium phosphate buffer, pH 6.0, to give a stock solution of convenient concentration. Further dilute with 10 percent potassium phosphate buffer, pH 6.0, to a reference concentration of 10 units of polymyxin per milliliter. Proceed as directed in § 148p.1(b)(1), except add 300 milligrams of thioglycolic acid to each liter of agar used for the seed layer. The polymyxin content is satisfactory if it is not less than 90 percent and not more than 125 percent of the number of units of polymyxin that it is represented to contain.

(ii) *Gramicidin content.* Proceed as directed in § 148f.1(b)(1) of this chapter, except prepare the sample for assay as follows: Remove an accurately measured representative portion and dilute with 95 percent alcohol to give a stock solution of convenient concentration. Further dilute with 95 percent alcohol to the prescribed reference concentration. The content of gramicidin is satisfactory if it is not less than 90 percent and not more than 125 percent of the number of milligrams of gramicidin that it is represented to contain.

(2) *pH.* Proceed as directed in § 141a.5(b) of this chapter, using the undiluted sample.

§ 148r.2 Tyrothricin solution.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Tyrothricin solution is tyrothricin and a suitable preservative dissolved in a vehicle of alcohol and propylene glycol. Each milliliter contains 25 milligrams of tyrothricin. The pH of a solution prepared by mixing 1 milliliter of the concentrate with 49 milliliters of distilled water is not less than 5.0 and not more than 6.5. The tyrothricin used conforms to the standards prescribed by § 148r.1(a)(1). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Requests for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The tyrothricin used in making the batch for potency, moisture, and identity.

(*b*) The batch for potency and pH.

(ii) Samples required:

(a) The tyrothricin used in making the batch: Five packages, each containing approximately 300 milligrams.

(b) The batch: A minimum of five immediate containers.

(c) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 1 gram.

(4) *Fees.* $4.00 for each immediate container or package in the samples submitted in accordance with subparagraph (3)(ii) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148r.1 (b)(1), except prepare the sample for assay as follows: Transfer the contents of a vial to a 1,000-milliliter volumetric flask, adjust to volume with distilled water, and mix well. Make proper estimated dilutions of an aliquot to the reference concentration with 95 percent alcohol. Its content of tyrothricin is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of milligrams of tyrothricin that it is represented to contain.

(2) *pH.* Proceed as directed in § 141a.5(b) of this chapter, except use a solution prepared by mixing 1 milliliter of the concentrate with 49 milliliters of distilled water.

§ 148r.3 Tyrothricin-antipyrine-benzocaine-hexylresorcinol otic solution.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Tyrothricin-antipyrine-benzocaine-hexylresorcinol otic solution is tyrothricin, antipyrine, benzocaine, and hexylresorcinol dissolved in a vehicle of propylene glycol and glycerin. Each milliliter contains 0.5 milligrams of tyrothricin, 50 milligrams of antipyrine, 12.5 milligrams of benzocaine, and 1.0 milligram of hexylresorcinol. The moisture content is not more than 2.0 percent. The pH is not less than 5.5 and not more than 7.5. The tyrothricin used conforms to the standards prescribed by § 148r.1(a)(1). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Requests for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(a) The tyrothricin used in making the batch for potency, moisture, and identity.

(b) The batch for potency, moisture, and pH.

(ii) Samples required:

(a) The tyrothricin used in making the batch: Five packages, each containing approximately 300 milligrams.

(b) The batch: A minimum of five immediate containers.

(c) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(4) *Fees.* $4.00 for each immediate container or package in the samples submitted in accordance with subparagraph (3)(ii) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148r.1 (b)(1), except prepare the sample for assay as follows: Remove an accurately measured representative portion with a suitable syringe and appropriately dilute with 95 percent alcohol to yield a stock solution of convenient concentration. Make proper estimated dilutions with 95 percent alcohol to the prescribed reference concentration. Its content of tyrothricin is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of milligrams of tyrothricin that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.8(b) of this chapter.

(3) *pH.* Proceed as directed in § 141a.5(b) of this chapter using the undiluted sample.

§ 148r.4 Tyrothricin cream.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Tyrothricin cream is tyrothricin, with or without one or more suitable solvents, surfactants, and preservatives, in a suitable cream base. Each gram contains 0.5 milligram of tyrothricin. The tyrothricin used conforms to the standards prescribed by § 148r.1(a)(1). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(i) On the label of the immediate container and on the outside wrapper or container, if any:

(a) The batch mark.

(b) The name and quantity of each active ingredient contained in the drug.

(c) An expiration date that is 12 months after the month during which the batch was certified.

(ii) On the label of the immediate container or other labeling attached to or within the package, adequate directions for lay use of the drug.

(3) *Requests for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(a) The tyrothricin used in making the batch for potency, moisture, and identity.

(b) The batch for potency.

(ii) Samples required:

(a) The tyrothricin used in making the batch: Five packages, each containing approximately 300 milligrams.

(b) The batch: A minimum of five immediate containers.

(c) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(4) *Fees.* $4.00 for each immediate container or package in the samples submitted in accordance with subparagraph (3)(ii) of this paragraph.

(b) *Tests and methods of assay; potency.* Proceed as directed in § 148r.1 (b)(1), except prepare the sample for assay as follows: Transfer an accurately weighed representative portion to a separatory funnel and add 25 milliliters of petroleum ether. Shake the contents until the cream is dispersed. Add 50 milliliters of 80 percent ethyl alcohol and shake well. Allow the phases to separate. Transfer the alcohol phase to a second separatory funnel. Add 25 milliliters of petroleum ether, shake for 2 or 3 minutes and allow the phases to separate. Repeat the extraction again if necessary. Collect the alcohol layer in a 100-milliliter volumetric flask, adjust to mark with 80 percent alcohol, and shake well. Make proper estimated dilutions to the reference concentration with 95 percent alcohol. Its content of tyrothricin is satisfacotry if it is not less than 90 percent and not more than 140 percent of the number of milligrams of tyrothricin that it is represented to contain.

§ 148r.5 Tyrothricin-methapyrilene hydrochloride-benzocaine cream.

Tyrothricin-methapyrilene hydrochloride-benzocaine cream conforms to all requirements and is subject to all procedures prescribed by § 148r.4 for tyrothricin cream, except that each gram of cream contains 0.25 milligram of tyrothricin, 20 milligrams of methapyrilene hydrochloride, and 20 milligrams of benzocaine.

§ 148r.6 Tyrothricin-phenylpropanolamine hydrochloride nasal solution.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Tyrothricin-phenylpropanolamine hydrochloride nasal solution is tyrothricin and phenylpropanolamine hydrochloride dissolved in an aqueous vehicle, with one or more suitable solvents, buffer substances, and colorings. Each milliliter contains 0.2 milligram of tyrothricin and 15 milligrams of phenylpropanolamine hydrochloride. Its pH is not less than 5.5 and not more than 6.5. The tyrothricin used conforms to the standards prescribed by § 148r.1(a)(1). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(i) On the label of the immediate container and on the outside wrapper or container, if any:

(a) The batch mark.

(b) The name and quantity of each active ingredient contained in the drug.

(c) An expiration date that is 12 months after the month during which the batch was certified.

(ii) On the label of the immediate container or other labeling attached to or within the package, adequate directions for lay use of the drug.

(3) *Requests for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The tyrothricin used in making the batch for potency, moisture, and identity.

(*b*) The batch for potency and pH.

(ii) Samples required:

(*a*) The tyrothricin used in making the batch: Five packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of five immediate containers.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(4) *Fees.* $4.00 for each immediate container or package in the samples submitted in accordance with subparagraph (3) (ii) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148r.3 (b) (1). Its content of tyrothricin is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of tyrothricin that it is represented to contain.

(2) *pH.* Proceed as directed in § 141a.5(b) of this chapter.

§ 148r.7 Tyrothricin - pantothenyl alcohol mouthwash.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Tyrothricin-pantothenyl alcohol mouthwash is tyrothricin and pantothenyl alcohol with one or more suitable solvents, surfactants, colorings, and flavorings in an aqueous vehicle. Each milliliter contains 0.2 milligram of tyrothricin and 0.2 milligram of pantothenyl alcohol. Its pH is not less than 5.0 and not more than 7.0. The tyrothricin used conforms to the standards prescribed by § 148r.1(a) (1). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(i) On the label of the immediate container and on the outside wrapper or container, if any:

(*a*) The batch mark.

(*b*) The name and quantity of each active ingredient contained in the drug.

(*c*) An expiration date that is 12 months after the month during which the batch was certified.

(ii) On the label of the immediate container or other labeling attached to or within the package, adequate directions for lay use of the drug.

(3) *Requests for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The tyrothricin used in making the batch for potency, moisture, and identity.

(*b*) The batch for potency and pH.

(ii) Samples required:

(*a*) The tyrothricin used in making the batch: Five packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of five immediate containers.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(4) *Fees.* $4.00 for each immediate container or package in the samples submitted in accordance with subparagraph (3) (ii) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148r.3-(b) (1). Its content of tyrothricin is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of milligrams of tyrothricin that it is represented to contain.

(2) *pH.* Proceed as directed in § 141a.5(b) of this chapter, except use the undiluted solution.

§ 148r.8 Tyrothricin-benzocaine troches; tyrothricin-propyl *p*-aminobenzoate troches.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Each tyrothricin-benzocaine troche contains 1.0 milligram of tyrothricin and 5.0 milligrams of benzocaine, with or without one or more suitable fillers, binders, lubricants, colorings, and flavorings. Each tyrothricin-propyl *p*-aminobenzoate troche contains 2.0 milligrams of tyrothricin and 2.0 milligrams of propyl *p*-aminobenzoate, with or without one or more suitable and harmless fillers, binders, lubricants, colorings, and flavorings. The moisture content is not more than 1.5 percent. The tyrothricin used conforms to the standards prescribed by § 148r.1(a) (1). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(i) On the label of the immediate container and on the outside wrapper or container, if any:

(*a*) The batch mark.

(*b*) The name and quantity of each active ingredient contained in the drug.

(*c*) An expiration date that is 12 months after the month during which the batch was certified.

(ii) On the label of the immediate container or other labeling attached to or within the package, adequate directions for lay use of the drug.

(3) *Requests for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The tyrothricin used in making the batch for potency, moisture, and identity.

(*b*) The batch for potency and moisture.

(ii) Samples required:

(*a*) The tyrothricin used in making the batch: Five packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of 30 troches.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(4) *Fees.* $0.75 for each troche submitted in accordance with subparagraph (3) (ii) (*b*) of this paragraph; $4.00 for each package in the samples submitted in accordance with subparagraph (3) (ii) (*a*) and (*c*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148r.1(b) (1), except prepare the sample for assay as follows: Place a representative number of troches into a flask of suitable size. Add a quantity of 95 percent ethyl alcohol that will give a stock solution of convenient concentration. Stopper the flask and place on a mechanical shaker. Allow to shake until the troches are dissolved. Make proper estimated dilutions with 95 percent alcohol to the reference concentration. Its content of tyrothricin is satisfactory if it is not less than 90 percent and not more than 140 percent of the number of milligrams of tyrothricin that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter.

§ 148r.9 Tyrothricin - triethanolamine polypeptide cocoate condensate solution.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality and purity.* Tyrothricin-triethanolamine polypeptide cocoate condensate solution contains, per milliliter, 1.0 milligram of tyrothricin and 120 milligrams of triethanolamine polypeptide cocoate, with one or more suitable solubilizing agents, perfumes, buffer substances, and preservatives, in distilled water. Its pH is not less than 5.5 and not more than 6.5. The tyrothricin used conforms to the standards prescribed by § 148r.1(a) (1). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Requests for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The tyrothricin used in making the batch for potency, moisture, and identity.

(*b*) The batch for potency and pH.

(ii) Samples required:

(*a*) The tyrothricin used in making the batch: Five packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of five immediate containers.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(4) *Fees.* $4.00 for each immediate container or package in the samples submitted in accordance with subparagraph (3) (ii) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148r.3 (b) (1). Its content of tyrothricin is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of milligrams of tyrothricin that it is represented to contain.

(2) *pH.* Proceed as directed in § 141a.5(b) of this chapter, using the undiluted solution.

§ 148r.10 Tyrothricin-nitrofurazone adhesive bandage.

(a) *Requirements for certification—*(1) *Standards of identity, strength, quality, and purity.* Tyrothricin-nitrofurazone adhesive bandage is a gauze or flannel compress impregnated with tyrothricin and nitrofurazone, covered with a transparent porous material, and affixed to a perforated pliable plastic strip which is coated on one surface with a pressure-sensitive adhesive. The folded gauze compress has dimensions of ⅞ by 1 inch, ⅝ by 1 inch, $^{23}/_{32}$ by $^{9}/_{16}$ inch, or $^{9}/_{32}$ by ½ inch. The flannel compress is round with a diameter of 10 millimeters. The bandage is enclosed in a sealed paper wrapper. Each gram of gauze or flannel compress contains not less than 0.1 milligram each of tyrothricin and nitrofurazone. It is sterile. The tyrothricin used conforms to the standards prescribed by § 148r.1(a)(1). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed by such official compendium.

(2) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(i) On the label of the immediate container and on the outside wrapper or container, if any:

(*a*) The batch mark.

(*b*) The name and quantity of each active ingredient contained in the drug.

(*c*) An expiration date that is 12 months after the month during which the batch was certified.

(ii) On the label of the immediate container or other labeling attached to or within the package, adequate directions for lay use.

(3) *Requests for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The tyrothricin used in making the batch for potency, moisture, and identity.

(*b*) The impregnated gauze or flannel used in making the batch for potency.

(*c*) The batch for potency and sterility.

(ii) Samples required:

(*a*) The tyrothricin used in making the batch: Five packages, each containing approximately 300 milligrams.

(*b*) The impregnated gauze or flannel used in making the batch: Five pieces, each approximately 1 square yard in area.

(*c*) The batch:

(*1*) For potency testing: 30 bandages each of the gauze type and of the flannel type.

(*2*) For sterility testing: 10 bandages of the ¾- by 3-inch size from each sterilizer load or, if such size is not included, 10 bandages of the largest size bandage from each sterilizer load.

(4) *Fees.* $4.00 for each sample submitted in accordance with subparagraph (3)(ii)(*a*) of this paragraph; $6.00 for each sample submitted in accordance with subparagraph (3)(ii)(*b*) of this paragraph; $1.00 for each bandage submitted in accordance with subparagraph (3)(ii)(*c*) of this paragraph.

(b) *Tests and methods of assay—*(1) *Potency.* Proceed as directed in § 148r.1(b)(1), except prepare the sample for assay as follows: Dip a representative number of bandages in a mixture containing equal parts of petroleum ether and carbon tetrachloride in order to remove the compresses. Allow the compresses to air dry for 5 minutes. Accurately weigh 0.4 gram of gauze, or 0.1 gram if the compress is composed of flannel. If the sample is the impregnated gauze or flannel used in making the bandages, cut out approximately 12 square inches of the material and weigh it accurately. Place the weighed sample in a glass-stoppered flask and add sufficient 95 percent ethyl alcohol to give a stock solution of convenient concentration. Stopper the flask and place it in a 37° C. incubator for ½ hour. Further dilute the stock solution with sufficient 95 percent ethyl alcohol to obtain the prescribed reference concentration of tyrothricin. Its content of tyrothricin is satisfactory if it is not less than 0.1 milligram per gram of material.

(2) *Sterility.* Use 10 bandages of the ¾- by 3-inch size and proceed as directed in § 141.2(e)(2) of this chapter except aseptically remove the paper wrapper and lift, but do not remove, both sections of the protective, translucent plastic strips until the compress is exposed. Place one such bandage into each of five tubes of medium A and one into each of five tubes of medium E.

Dated: October 9, 1964.

GEO. P. LARRICK,
Commissioner of Food and Drugs.

[F.R. Doc. 64-10545; Filed, Oct. 16, 1964; 8:45 a.m.]